Proposed 506J Device List by Medical Specialty Panel

Preface

To facilitate the Advisory Committee meeting discussion and the Panel's review of the proposed 506J Device List, this document organizes the product codes on the proposed 506J Device List by FDA medical specialty panel. These panels are further described in the Code of Federal Regulations (CFR), Parts 862-892.[1]

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Anesthesiology

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Anesthesiology	Airway Connectors, Tubing, and Circuits	BYX	Tubing, Pressure And Accessories	868.5860 Pressure tubing and accessories. Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.

[1] *See* Device Classification Panels, https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Anesthesiology	Carbon Dioxide Absorbent	CBL	Absorbent, Carbon-Dioxide	868.5300 Carbon dioxide absorbent. A carbon dioxide absorbent is a device intended for medical purposes that consists of an absorbent material (e.g., soda lime) that is intended to remove carbon dioxide from the gases in the breathing circuit.
Anesthesiology	Condensers	BYD	Condenser, Heat And Moisture (Artificial Nose)	868.5375 Heat and moisture condenser (artificial nose). A heat and moisture condenser (artificial nose) is a device intended to be positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient.
Anesthesiology	Endotracheal Tubes (ETTs)	BSK	Cuff, Tracheal Tube, Inflatable	868.5750 Inflatable tracheal tube cuff. An inflatable tracheal tube cuff is a device used to provide an airtight seal between a tracheal tube and a patient's trachea.
Anesthesiology	Endotracheal Tubes (ETTs)	BTR	Tube, Tracheal (W/Wo Connector)	868.5730 Tracheal tube. A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.
Anesthesiology	Flowmeters	CAX	Flowmeter, Tube, Thorpe, Back-Pressure Compensated	868.2340 Compensated thorpe tube flowmeter. A compensated thorpe tube flowmeter is a device intended for medical purposes that is used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.
Anesthesiology	Gas Analyzers	CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	868.1400 Carbon dioxide gas analyzer. A carbon dioxide gas analyzer is a device intended to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory, circulatory, and metabolic status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, or mass spectrometry.
Anesthesiology	Gas Analyzers	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase	868.1720 Oxygen gas analyzer. An oxygen gas analyzer is a device intended to measure the concentration of oxygen in respiratory gases by techniques such as mass spectrometry, polarography, thermal conductivity, or gas chromatography. This

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				generic type of device also includes paramagnetic analyzers.
Anesthesiology	Gas Mixers	BZR	Mixer, Breathing Gases, Anesthesia Inhalation	868.5330 Breathing gas mixer. A breathing gas mixer is a device intended for use in conjunction with a respiratory support apparatus to control the mixing of gases that are to be breathed by a patient.
Anesthesiology	High-Flow Oxygen Delivery Devices	QAV	High Flow/High Velocity Humidified Oxygen Delivery Device	868.5454 High flow humidified oxygen delivery device. A high flow humidified oxygen delivery device is a prescription device that delivers high flow oxygen with humidification for patients who are suffering from respiratory distress and/or hypoxemia.
Anesthesiology	Humidifiers	BTT	Humidifier, Respiratory Gas, (Direct Patient Interface)	868.5450 Respiratory gas humidifier. A respiratory gas humidifier is a device that is intended to add moisture to, and sometimes to warm, the breathing gases for administration to a patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device.
Anesthesiology	Laryngoscopes	CCW	Laryngoscope, Rigid	868.5540 Rigid laryngoscope. A rigid laryngoscope is a device used to examine and visualize a patient's upper airway and aid placement of a tracheal tube.
Anesthesiology	Manual Resuscitators	NHK	Resuscitator, Manual, Non Self-Inflating	868.5905 Noncontinuous ventilator (IPPB). A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing.
Anesthesiology	Mechanical Ventilators	BZD	Ventilator, Non-Continuous (Respirator)	868.5905 Noncontinuous ventilator (IPPB). A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing.
Anesthesiology	Mechanical Ventilators	CBK	Ventilator, Continuous, Facility Use	868.5895 Continuous ventilator. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

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Anesthesiology	Mechanical Ventilators	LSZ	Ventilator, High Frequency	[No CFR Description or FDA Product Classification Database definition.]
Anesthesiology	Mechanical Ventilators	MNS	Ventilator, Continuous, Non-Life-Supporting	868.5895 Continuous ventilator. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.
Anesthesiology	Mechanical Ventilators	MNT	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	868.5895 Continuous ventilator. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.
Anesthesiology	Mechanical Ventilators	QBY	Positive Airway Pressure System	868.5273 Positive airway pressure delivery system. A positive airway pressure delivery system is a prescription noninvasive ventilatory device that delivers expiratory positive airway pressure for patients suffering from obstructive sleep apnea. The system also provides positive airway pressure during incipient apnea. The system may include a dedicated flow generator and a patient interface.
Anesthesiology	Nasal Cannulas	BZB	Catheter, Nasal, Oxygen	868.5350 Nasal oxygen catheter. A nasal oxygen catheter is a device intended to be inserted through a patient's nostril to administer oxygen.
Anesthesiology	Nasal Cannulas	CAT	Cannula, Nasal, Oxygen	868.5340 Nasal oxygen cannula. A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils.
Anesthesiology	Nasopharyngeal Airways	BTQ	Airway, Nasopharyngeal	868.5100 Nasopharyngeal airway. A nasopharyngeal airway is a device used to aid breathing by means of a tube inserted into a patient's pharynx through the nose to provide a patent airway.
Anesthesiology	Nebulizers	CAF	Nebulizer (Direct Patient Interface)	868.5630 Nebulizer. A nebulizer is a device intended to spray liquids in aerosol form into gases that are delivered directly to the patient for

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				breathing. Heated, ultrasonic, gas, venturi, and refillable nebulizers are included in this generic type of device.
Anesthesiology	Oropharyngeal Airways	CAE	Airway, Oropharyngeal, Anesthesiology	868.5110 Oropharyngeal airway. An oropharyngeal airway is a device inserted into a patient's pharynx through the mouth to provide a patent airway.
Anesthesiology	Oximeters	DQA	Oximeter	870.2700 Oximeter. An oximeter is a device used to transmit radiation at a known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.
Anesthesiology	Oxygen Masks	BYG	Mask, Oxygen	868.5580 Oxygen mask. An oxygen mask is a device placed over a patient's nose, mouth, or tracheostomy to administer oxygen or aerosols.
Anesthesiology	Oxygen Masks	KGB	Mask, Oxygen, Non-Rebreathing	868.5570 Nonrebreathing mask. A nonrebreathing mask is a device fitting over a patient's face to administer oxygen. It utilizes one-way valves to prevent the patient from rebreathing previously exhaled gases.
Anesthesiology	Portable Oxygen Sources	BYJ	Unit, Liquid-Oxygen, Portable	868.5655 Portable liquid oxygen unit. A portable liquid oxygen unit is a portable, thermally insulated container of liquid oxygen that is intended to supplement gases to be inhaled by a patient, is sometimes accompanied by tubing and an oxygen mask. An empty portable liquid oxygen unit is a device, while the oxygen contained therein is a drug.
Anesthesiology	Portable Oxygen Sources	CAW	Generator, Oxygen, Portable	868.5440 Portable oxygen generator. A portable oxygen generator is a device that is intended to release oxygen for respiratory therapy by means of either a chemical reaction or physical means (e.g., a molecular sieve).
Anesthesiology	Positive End Expiratory Pressure (PEEP) Attachments	BYE	Attachment, Breathing, Positive End Expiratory Pressure	868.5965 Positive end expiratory pressure breathing attachment. A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above

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				atmospheric pressure at the end of exhalation.
Anesthesiology	Spinal Needles	MIA	Needle, Spinal, Short Term	868.5150 Anesthesia conduction needle. An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.
Anesthesiology	Stylets and Endotracheal Tube (ETT) Changers	BSR	Stylet, Tracheal Tube	868.5790 Tracheal tube stylet. A tracheal tube stylet is a device used temporarily to make rigid a flexible tracheal tube to aid its insertion into a patient.
Anesthesiology	Stylets and Endotracheal Tube (ETT) Changers	LNZ	Changer, Tube, Endotracheal	868.5730 Tracheal tube. A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.
Anesthesiology	Suction Tubes and Catheters	BSY	Catheters, Suction, Tracheobronchial	868.6810 Tracheobronchial suction catheter. A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.
Anesthesiology	Suction Tubes and Catheters	DWM	Apparatus, Suction, Patient Care	870.5050 Patient care suction apparatus. A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.
Anesthesiology	Tracheostomy Tubes	BTO	Tube, Tracheostomy (W/Wo Connector)	868.5800 Tracheostomy tube and tube cuff. A tracheostomy tube and tube cuff is a device intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff may be a separate or integral part of the tracheostomy tube and is, when inflated, intended to establish a seal between the tracheal wall and the tracheostomy tube. The cuff is used to prevent the patient's aspiration of substances, such as blood or vomit, or to provide a means for positive-pressure ventilation of the patient. This device is made of either stainless steel or plastic.
Anesthesiology	Tracheostomy Tubes	JOH	Tube Tracheostomy And Tube Cuff	868.5800 Tracheostomy tube and tube cuff. A tracheostomy tube and tube cuff is a device intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff may be a separate or integral part of the tracheostomy tube and is, when inflated,

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				intended to establish a seal between the tracheal wall and the tracheostomy tube. The cuff is used to prevent the patient's aspiration of substances, such as blood or vomit, or to provide a means for positive-pressure ventilation of the patient. This device is made of either stainless steel or plastic.
Anesthesiology	Valves	CBP	Valve, Non-Rebreathing	868.5870 Nonrebreathing valve. A nonrebreathing valve is a one-way valve that directs breathing gas flow to the patient and vents exhaled gases into the atmosphere.

Cardiovascular

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Cardiovascular	Angioplasty Catheters	DRB	Stylet, Catheter	870.1380 Catheter stylet. A catheter stylet is a wire that is run through a catheter or cannula to render it stiff.
Cardiovascular	Angioplasty Catheters	DYB	Introducer, Catheter	870.1340 Catheter introducer. A catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.
Cardiovascular	Angioplasty Catheters	ONU	Drug-Eluting Peripheral Transluminal Angioplasty Catheter	[No CFR Description; definition provided from FDA Product Classification Database] A drug-eluting peripheral transluminal angioplasty catheter is a combination product intended for balloon dilatation of peripheral vasculature to establish or maintain patency. A drug-eluting PTA catheter delivers a drug to the vessel as part of the angioplasty procedure and is intended to inhibit restenosis. Intended to provide percutaneous transluminal angioplasty of lesions in peripheral arteries including iliac, popliteal, femoral, and iliofemoral.
Cardiovascular	Automated External Defibrillators (AEDs)	MKJ	Automated External Defibrillators (Non-Wearable)	870.5310 Automated external defibrillator system. An automated external defibrillator (AED) system consists of an AED and those accessories necessary for the AED to

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				detect and interpret an electrocardiogram and deliver an electrical shock (e.g., battery, pad electrode, adapter, and hardware key for pediatric use). An AED system analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.
Cardiovascular	Blood Pressure Cuff	DXQ	Blood Pressure Cuff	870.1120 Blood pressure cuff. A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.
Cardiovascular	Blood Pressure System	DXN	System, Measurement, Blood-Pressure, Non-Invasive	870.1130 Noninvasive blood pressure measurement system. A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through the use of transducers placed on the surface of the body.
Cardiovascular	Cables	DSA	Cable, Transducer And Electrode, Patient, (Including Connector)	870.2900 Patient transducer and electrode cable (including connector). A patient transducer and electrode cable (including connector) is an electrical conductor used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DRY	Monitor, Blood-Gas, On-Line, Cardiopulmonary Bypass	870.4330 Cardiopulmonary bypass on-line blood gas monitor. A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTL	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass	870.4290 Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting. A cardiopulmonary bypass adaptor, stopcock, manifold, or fitting is a device

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTM	Filter, Blood, Cardiopulmonary Bypass, Arterial Line	870.4260 Cardiopulmonary bypass arterial line blood filter. A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTN	Reservoir, Blood, Cardiopulmonary Bypass	870.4400 Cardiopulmonary bypass blood reservoir. A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve supply of blood in the bypass circulation.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTP	Defoamer, Cardiopulmonary Bypass	870.4230 Cardiopulmonary bypass defoamer. A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiopulmonary bypass surgery to remove gas bubbles from the blood.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTQ	Console, Heart-Lung Machine, Cardiopulmonary Bypass	870.4220 Cardiopulmonary bypass heart-lung machine console. A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTR	Heat-Exchanger, Cardiopulmonary Bypass	870.4240 Cardiopulmonary bypass heat exchanger. A cardiopulmonary bypass heat exchanger is a device, consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				perfusion fluid flowing through the device.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTS	Sucker, Cardiotomy Return, Cardiopulmonary Bypass	870.4420 Cardiopulmonary bypass cardiotomy return sucker. A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTW	Monitor And/Or Control, Level Sensing, Cardiopulmonary Bypass	870.4340 Cardiopulmonary bypass level sensing monitor and/or control. A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTX	Gas Control Unit, Cardiopulmonary Bypass	870.4300 Cardiopulmonary bypass gas control unit. A cardiopulmonary bypass gas control unit is a device used to control and measure the flow of gas into the oxygenator. The device is calibrated for a specific gas.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTY	Sensor, Blood-Gas, In-Line, Cardiopulmonary Bypass	870.4410 Cardiopulmonary bypass in-line blood gas sensor. A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DTZ	Oxygenator, Cardiopulmonary Bypass	870.4350 Cardiopulmonary bypass oxygenator. A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DWA	Control, Pump Speed, Cardiopulmonary Bypass	870.4380 Cardiopulmonary bypass pump speed control. A cardiopulmonary bypass pump speed control is a device used that incorporates an electrical system or a mechanical system, or both, and is used to control the speed of blood pumps used in cardiopulmonary bypass surgery.

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Cardiovascular	Cardiopulmonary Bypass-related Devices	DWB	Pump, Blood, Cardiopulmonary Bypass, Roller Type	870.4370 Roller-type cardiopulmonary bypass blood pump. A roller-type cardiopulmonary bypass blood pump is a device that uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DWC	Controller, Temperature, Cardiopulmonary Bypass	870.4250 Cardiopulmonary bypass temperature controller. A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DWD	Suction Control, Intracardiac, Cardiopulmonary Bypass	870.4430 Cardiopulmonary bypass intracardiac suction control. A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DWE	Tubing, Pump, Cardiopulmonary Bypass	870.4390 Cardiopulmonary bypass pump tubing. A cardiopulmonary bypass pump tubing is polymeric tubing which is used in the blood pump head and which is cyclically compressed by the pump to cause the blood to flow through the cardiopulmonary bypass circuit.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DWF	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass	870.4210 Cardiopulmonary bypass vascular catheter, cannula, or tubing. A cardiopulmonary bypass vascular catheter, cannula, or tubing is a device used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and to interconnect the catheters and cannulas with an oxygenator. The device includes accessory bypass equipment.
Cardiovascular	Cardiopulmonary Bypass-related Devices	DXS	Gauge, Pressure, Coronary, Cardiopulmonary Bypass	870.4310 Cardiopulmonary bypass coronary pressure gauge. A cardiopulmonary bypass coronary pressure gauge is a device used in cardiopulmonary bypass surgery to measure the pressure of the blood perfusing the coronary arteries.

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Cardiovascular	Cardiopulmonary Bypass-related Devices	JOD	Filter, Blood, Cardiotomy Suction Line, Cardiopulmonary Bypass	870.4270 Cardiopulmonary bypass cardiotomy suction line blood filter. A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.
Cardiovascular	Cardiopulmonary Bypass-related Devices	KFM	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type	870.4360 Nonroller-type blood pump. A nonroller-type cardiopulmonary and circulatory bypass blood pump is a prescription device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:
Cardiovascular	Cardiopulmonary Bypass-related Devices	KRJ	Filter, Prebypass, Cardiopulmonary Bypass	870.4280 Cardiopulmonary prebypass filter. A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not used to filter blood.
Cardiovascular	Cardiopulmonary Bypass-related Devices	KRL	Detector, Bubble, Cardiopulmonary Bypass	870.4205 Cardiopulmonary bypass bubble detector. A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit
Cardiovascular	Cardiopulmonary Bypass-related Devices	MJJ	Cpb Check Valve, Retrograde Flow, In-Line	870.4400 Cardiopulmonary bypass blood reservoir. A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve supply of blood in the bypass circulation.
Cardiovascular	Cardiopulmonary Bypass-related Devices	MNJ	Valve, Pressure Relief, Cardiopulmonary Bypass	870.4400 Cardiopulmonary bypass blood reservoir. A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				circulation devices to hold a reserve supply of blood in the bypass circulation.
Cardiovascular	Catheters & Ports	DQX	Wire, Guide, Catheter	870.1330 Catheter guide wire. A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.
Cardiovascular	Catheters & Ports	DQY	Catheter, Percutaneous	870.1250 Percutaneous catheter. A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.
Cardiovascular	Catheters & Ports	LIT	Catheter, Angioplasty, Peripheral, Transluminal	870.1250 Percutaneous catheter. A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.
Cardiovascular	Catheters & Ports	LOX	Catheters, Transluminal Coronary Angioplasty, Percutaneous	870.5100 Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter. A PTCA catheter is a device that operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. A PTCA balloon catheter has a single or double lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use. A PTCA catheter is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				stent restenosis (ISR) and/or post-deployment stent expansion.
Cardiovascular	Electrocardiogram (ECG) System	DPS	Electrocardiograph	870.2340 Electrocardiograph. An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart.
Cardiovascular	Electrocardiogram (ECG) System	DRX	Electrode, Electrocardiograph	870.2360 Electrocardiograph electrode. An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.
Cardiovascular	Endovascular Graft Systems	MIH	System, Endovascular Graft, Aortic Aneurysm Treatment	[No CFR Description or FDA Product Classification Database definition.]
Cardiovascular	Endovascular Graft Systems	QSK	Hybrid Stent Graft, Thoracic Aortic Lesion Treatment	[No CFR Description; definition provided from FDA Product Classification Database] Repair or replacement of damaged or diseased vessel of the aortic arch and descending thoracic aorta, with or without involvement of ascending aorta, using vascular grafts and/or stent grafts placed during open surgical repair.
Cardiovascular	Extracorporeal Carbon Dioxide Removal System	QOH	Extracorporeal System For Carbon Dioxide Removal	870.4150 Extracorporeal system for carbon dioxide removal. An extracorporeal system for carbon dioxide removal is a system of devices and accessories that provides assisted extracorporeal carbon dioxide removal from the patient's blood in patients with acute respiratory failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, a gas exchanger, blood pump, cannulae, tubing, filters, and other accessories (e.g., monitors, detectors, sensors, connectors).

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Cardiovascular	Extracorporeal Membrane Oxygenation (ECMO) Cannulas, System, and Blood Pump	PZS	Dual Lumen Ecmo Cannula	870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure. An extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary support (>6 hours) is a system of devices and accessories that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, an oxygenator, blood pump, heat exchanger, cannulae, tubing, filters, and other accessories (e.g., monitors, detectors, sensors, connectors).
Cardiovascular	Extracorporeal Membrane Oxygenation (ECMO) Cannulas, System, and Blood Pump	QHW	Single Lumen Ecmo Cannula	870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure. An extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary support (>6 hours) is a system of devices and accessories that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, an oxygenator, blood pump, heat exchanger, cannulae, tubing, filters, and other accessories (e.g.,

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				monitors, detectors, sensors, connectors).
Cardiovascular	Extracorporeal Membrane Oxygenation (ECMO) Cannulas, System, and Blood Pump	QJZ	Extracorporeal System For Long-Term Respiratory / Cardiopulmonary Failure	870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure. An extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary support (>6 hours) is a system of devices and accessories that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, an oxygenator, blood pump, heat exchanger, cannulae, tubing, filters, and other accessories (e.g., monitors, detectors, sensors, connectors).
Cardiovascular	Extracorporeal Membrane Oxygenation (ECMO) Cannulas, System, and Blood Pump	QNR	Blood Pump For Ecmo, Long-Term (> 6 Hours) Use	870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure. An extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary support (>6 hours) is a system of devices and accessories that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, an oxygenator, blood

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				pump, heat exchanger, cannulae, tubing, filters, and other accessories (e.g., monitors, detectors, sensors, connectors).
Cardiovascular	Intra-Aortic Balloon Pump (IABP) System	DSP	System, Balloon, Intra-Aortic And Control	870.3535 Intra-aortic balloon and control system. An intra-aortic balloon and control system is a prescription device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the cardiac cycle.
Cardiovascular	Oxygenator	BYS	Oxygenator, Long Term Support Greater Than 6 Hours	870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure. An extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary support (>6 hours) is a system of devices and accessories that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, an oxygenator, blood pump, heat exchanger, cannulae, tubing, filters, and other accessories (e.g., monitors, detectors, sensors, connectors).
Cardiovascular	Percutaneous Catheterization Dilators	DRE	Dilator, Vessel, For Percutaneous Catheterization	870.1310 Vessel dilator for percutaneous catheterization. A vessel dilator for percutaneous

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.
Cardiovascular	Physiological Monitors	MHX	Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms)	870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm). The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs.
Cardiovascular	Stents	NIM	Stent, Carotid	[No CFR Description; definition provided from FDA Product Classification Database] Stent, Carotid -- a metal scaffold placed via a delivery catheter into the carotid artery to maintain the lumen.
Cardiovascular	Stents	NIQ	Coronary Drug-Eluting Stent	[No CFR Description; definition provided from FDA Product Classification Database] Stent, coronary, drug-eluting -- a metal scaffold with a drug coating placed via a delivery catheter into the coronary artery or saphenous vein graft to maintain the lumen. The drug coating is intended to inhibit restenosis.
Cardiovascular	Stents	NIV	Coronary Covered Stent	[No CFR Description; definition provided from FDA Product Classification Database] Stent, coronary, covered -- a metal scaffold covered with material placed via a delivery catheter into the coronary artery or saphenous vein graft for the treatment of free perforations and/or to prevent dislodgement into the circulation of biological material from the vascular wall during or following placement of the device.
Cardiovascular	Stents	PNF	Aortic Stent	[No CFR Description; definition provided from FDA Product Classification Database] Coarctation of the Aorta.
Cardiovascular	Thermoregulatory Devices	DWJ	System, Thermal Regulating	870.5900 Thermal regulating system. A thermal regulating system is an external system consisting of a device

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				that is placed in contact with the patient and a temperature controller for the device. The system is used to regulate patient temperature.
Cardiovascular	Transfusion and Plasmapheresis Devices	CAC	Apparatus, Autotransfusion	868.5830 Autotransfusion apparatus. An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.
Cardiovascular	Ventricular Assist Devices (VADs)	OZD	Temporary Non-Roller Type Left Heart Support Blood Pump	[No CFR Description; definition provided from FDA Product Classification Database] A blood pump that provides temporary full or partial left heart support.
Cardiovascular	Ventricular Assist Devices (VADs)	PYX	Temporary Non-Roller Type Right Heart Support Blood Pump	870.4360 Nonroller-type blood pump. A nonroller-type cardiopulmonary and circulatory bypass blood pump is a prescription device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Clinical Chemistry and Clinical Toxicology

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Clinical Chemistry and Clinical Toxicology	Blood Gas	CHL	Electrode Measurement, Blood-Gases (Pco2, Po2) And Blood Ph	862.1120 Blood gases (PCO2, PO2) and blood pH test system. A blood gases (PCO2, PO2) and blood pH test system is a device intended to measure certain gases in blood, serum, plasma or pH of blood, serum, and plasma. Measurements of blood gases (PCO2, PO2) and blood pH are used in

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				the diagnosis and treatment of life-threatening acid-base disturbances.
Clinical Chemistry and Clinical Toxicology	Blood Gas	JFL	Ph Rate Measurement, Carbon-Dioxide	862.1160 Bicarbonate/carbon dioxide test system. A bicarbonate/carbon dioxide test system is a device intended to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.
Clinical Chemistry and Clinical Toxicology	Cardiac Enzymes	MMI	Immunoassay Method, Troponin Subunit	862.1215 Creatine phosphokinase/creatine kinase or isoenzymes test system. A creatine phosphokinase/creatine kinase or isoenzymes test system is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma and serum. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CDQ	Urease And Glutamic Dehydrogenase, Urea Nitrogen	862.1770 Urea nitrogen test system. A urea nitrogen test system is a device intended to measure urea nitrogen (an end-product of nitrogen metabolism) in whole blood, serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CDS	Electrode, Ion Specific, Urea Nitrogen	862.1770 Urea nitrogen test system. A urea nitrogen test system is a device intended to measure urea nitrogen (an end-product of nitrogen metabolism) in whole blood, serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CEJ	Tetraphenyl Borate, Colorimetry, Potassium	862.1600 Potassium test system. A potassium test system is a device intended to measure potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CEM	Electrode, Ion Specific, Potassium	862.1600 Potassium test system. A potassium test system is a device intended to measure potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CFR	Hexokinase, Glucose	862.1345 Glucose test system. A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CGA	Glucose Oxidase, Glucose	862.1345 Glucose test system. A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CGL	Electrode, Ion Based, Enzymatic, Creatinine	862.1225 Creatinine test system. A creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CGX	Alkaline Picrate, Colorimetry, Creatinine	862.1225 Creatinine test system. A creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CGZ	Electrode, Ion-Specific, Chloride	862.1170 Chloride test system. A chloride test system is a device intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CHG	Acid, Phosphoric-Tungstic (Spectrophotometric), Chloride	862.1170 Chloride test system. A chloride test system is a device intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CHJ	Mercuric Thiocyanate, Colorimetry, Chloride	862.1170 Chloride test system. A chloride test system is a device intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CHS	Coulometric Method, Carbon-Dioxide	862.1160 Bicarbonate/carbon dioxide test system. A bicarbonate/carbon dioxide test system is a device intended to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				serious disorders associated with changes in body acid-base balance.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CIC	Cresolphthalein Complexone, Calcium	862.1145 Calcium test system. A calcium test system is a device intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CIG	Diazo Colorimetry, Bilirubin	862.1110 Bilirubin (total or direct) test system. A bilirubin (total or direct) test system is a device intended to measure the levels of bilirubin (total or direct) in plasma or serum. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, if used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CIQ	Diazo, Ast/Sgot	862.1100 Aspartate amino transferase (AST/SGOT) test system. An aspartate amino transferase (AST/SGOT) test system is a device intended to measure the activity of the enzyme aspartate amino transferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CIS	Hydrazone Colorimetry, Ast/Sgot	862.1100 Aspartate amino transferase (AST/SGOT) test system. An aspartate amino transferase (AST/SGOT) test system is a device intended to measure the activity of the enzyme aspartate amino transferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma. Aspartate amino transferase measurements are used in

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				the diagnosis and treatment of certain types of liver and heart disease.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CIT	Nadh Oxidation/Nad Reduction, Ast/Sgot	862.1100 Aspartate amino transferase (AST/SGOT) test system. An aspartate amino transferase (AST/SGOT) test system is a device intended to measure the activity of the enzyme aspartate amino transferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CJY	Azo Dye, Calcium	862.1145 Calcium test system. A calcium test system is a device intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	CKA	Nadh Oxidation/Nad Reduction, Alt/Sgpt	862.1030 Alanine amino transferase (ALT/SGPT) test system. An alanine amino transferase (ALT/SGPT) test system is a device intended to measure the activity of the enzyme alanine amino transferase (ALT) (also known as a serum glutamic pyruvic transaminase or SGPT) in serum and plasma. Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	JFM	Enzymatic Method, Bilirubin	862.1110 Bilirubin (total or direct) test system. A bilirubin (total or direct) test system is a device intended to measure the levels of bilirubin (total or direct) in plasma or serum. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, if used in the diagnosis and treatment of liver,

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	JFP	Electrode, Ion Specific, Calcium	862.1145 Calcium test system. A calcium test system is a device intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	JFY	Enzymatic Method, Creatinine	862.1225 Creatinine test system. A creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	JGS	Electrode, Ion Specific, Sodium	862.1665 Sodium test system. A sodium test system is a device intended to measure sodium in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	KHS	Enzymatic, Carbon-Dioxide	862.1160 Bicarbonate/carbon dioxide test system. A bicarbonate/carbon dioxide test system is a device intended to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				serious disorders associated with changes in body acid-base balance.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	LFR	Glucose Dehydrogenase, Glucose	862.1345 Glucose test system. A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	MZU	System, Test, Sodium, Enzymatic Method	862.1665 Sodium test system. A sodium test system is a device intended to measure sodium in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
Clinical Chemistry and Clinical Toxicology	Complete Metabolic Panel (CMP) Tests	MZV	Test, System, Potassium, Enzymatic Method	862.1600 Potassium test system. A potassium test system is a device intended to measure potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
Clinical Chemistry and Clinical Toxicology	Glucose Sensors	MDS	Sensor, Glucose, Invasive	[No CFR Description; definition provided from FDA Product Classification Database] The device is a glucose-monitoring device indicated for detecting trends and tracking patterns in adults (age 18 and older) with diabetes. The device is indicated for use as an adjunctive device to complement, not

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				replace, information obtained from standard home glucose monitoring devices. The system aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.
Clinical Chemistry and Clinical Toxicology	Glucose Sensors	PQF	Sensor, Glucose, Invasive, Non-Adjunctive	[No CFR Description; definition provided from FDA Product Classification Database] A non-adjunctive invasive glucose sensor is intended to determine glucose levels, and the direction and rate of change of glucose levels in people with diabetes. The device is indicated to replace information obtained from standard blood glucose monitoring devices to make diabetes-related treatment decisions. The device also provides historical glucose information, facilitating long-term therapy adjustments.
Clinical Chemistry and Clinical Toxicology	Glucose Sensors	PZE	Sensor, Glucose, Invasive, Non-Adjunctive, Factory-Calibrated, User-Initiated	[No CFR Description; definition provided from FDA Product Classification Database] A subcutaneous factory calibrated, non-adjunctive, invasive, passive monitoring glucose sensor is intended to determine glucose levels and the direction and rate of change of glucose levels in people with diabetes. Calibrated at the point of manufacture and does not require or accept any user-entered calibration. Monitors glucose levels passively and only provides information, including alarms and alerts, in response to a user initiated action. The device is indicated to replace information obtained from standard blood glucose monitoring devices to make diabetes-related treatment decisions and also provides historical glucose information, facilitating long-term therapy adjustments.
Clinical Chemistry and Clinical Toxicology	Insulin Infusion Pumps	LZG	Pump, Infusion, Insulin	880.5725 Infusion pump. An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.
Clinical Chemistry and Clinical Toxicology	Insulin Infusion Pumps	OYC	Pump, Infusion, Insulin, To Be Used With Invasive Glucose Sensor	[No CFR Description; definition provided from FDA Product Classification Database] The insulin pump is intended to be used as a component of an invasive glucose device. The pump is designed to pump fluid (insulin) into a patient in a controlled manner as an aid in the management of diabetes mellitus in persons requiring insulin. It is intended to accept and display data from the glucose sensor.
Clinical Chemistry and Clinical Toxicology	Insulin Infusion Pumps	QFG	Alternate Controller Enabled Insulin Infusion Pump	880.5730 Alternate controller enabled infusion pump. An alternate controller enabled infusion pump (ACE pump) is a device intended for the infusion of drugs into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. ACE pumps are designed to reliably and securely communicate with external devices, such as automated drug dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE pumps are intended to be used both alone and in conjunction with digitally connected medical devices for the purpose of drug delivery.
Clinical Chemistry and Clinical Toxicology	Lactate Dehydrogenase	CFJ	Nad Reduction/Nadh Oxidation, Lactate Dehydrogenase	862.1440 Lactate dehydrogenase test system. A lactate dehydrogenase test system is a device intended to measure the activity of the enzyme lactate dehydrogenase in serum. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				diseases such as myocardial infarction, and tumors of the lung or kidneys.
Clinical Chemistry and Clinical Toxicology	Lactate Dehydrogenase	KHP	Acid, Lactic, Enzymatic Method	862.1450 Lactic acid test system. A lactic acid test system is a device intended to measure lactic acid in whole blood and plasma. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).
Clinical Chemistry and Clinical Toxicology	Magnesium	CFA	Electrode, Ion Specific, Magnesium	862.1495 Magnesium test system. A magnesium test system is a device intended to measure magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).
Clinical Chemistry and Clinical Toxicology	Magnesium	CFO	Titrimetric, Magnesium	862.1495 Magnesium test system. A magnesium test system is a device intended to measure magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).
Clinical Chemistry and Clinical Toxicology	Magnesium	JGJ	Photometric Method, Magnesium	862.1495 Magnesium test system. A magnesium test system is a device intended to measure magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).
Clinical Chemistry and Clinical Toxicology	Nucleic Acid Amplification Test System	OOI	Real Time Nucleic Acid Amplification System	862.2570 Instrumentation for clinical multiplex test systems. Instrumentation for clinical multiplex test systems is a device intended to measure and sort multiple signals generated by an assay from a clinical sample. This

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. Such instrumentation may be compatible with more than one specific assay. The device includes a signal reader unit, and may also integrate reagent handling, hybridization, washing, dedicated instrument control, and other hardware components, as well as raw data storage mechanisms, data acquisition software, and software to process detected signals.
Clinical Chemistry and Clinical Toxicology	Specimen Collection Devices	GIM	Tubes, Vacuum Sample, With Anticoagulant	862.1675 Blood specimen collection device. A blood specimen collection device is a device intended for medical purposes to collect and to handle blood specimens and to separate serum from nonserum (cellular) components prior to further testing. This generic type device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.
Clinical Chemistry and Clinical Toxicology	Specimen Collection Devices	JKA	Tubes, Vials, Systems, Serum Separators, Blood Collection	862.1675 Blood specimen collection device. A blood specimen collection device is a device intended for medical purposes to collect and to handle blood specimens and to separate serum from nonserum (cellular) components prior to further testing. This generic type device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.
Clinical Chemistry and Clinical Toxicology	Specimen Collection Devices	PJC	Newborn Screening Specimen Collection Paper	862.1675 Blood specimen collection device. A blood specimen collection device is a device intended for medical purposes to collect and to handle blood specimens and to separate serum from nonserum (cellular) components prior to further testing. This generic type device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Clinical Chemistry and Clinical Toxicology	Specimen Collection Devices	PJE	Blood/Plasma Collection Device For Dna Testing	862.1675 Blood specimen collection device. A blood specimen collection device is a device intended for medical purposes to collect and to handle blood specimens and to separate serum from nonserum (cellular) components prior to further testing. This generic type device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.

Ear, Nose, and Throat

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Ear, Nose, and Throat	Bronchoscope Accessories	KTI	Bronchoscope Accessory	874.4680 Bronchoscope (flexible or rigid) and accessories. A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the bronchoscope and is intended to examine or treat the larynx and tracheobronchial tree. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, nonrigid bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube, but excludes the fiberoptic light source and carrier.
Ear, Nose, and Throat	Bronchoscopes	EOQ	Bronchoscope (Flexible Or Rigid)	874.4680 Bronchoscope (flexible or rigid) and accessories. A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				devices which attach to the bronchoscope and is intended to examine or treat the larynx and tracheobronchial tree. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, nonrigid bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube, but excludes the fiberoptic light source and carrier.
Ear, Nose, and Throat	Suction Tubes and Catheters	KCB	Tube, Tonsil Suction	874.4420 Ear, nose, and throat manual surgical instrument. An ear, nose, and throat manual surgical instrument is one of a variety of devices intended for use in surgical procedures to examine or treat the bronchus, esophagus, trachea, larynx, pharynx, nasal and paranasal sinus, or ear. This generic type of device includes the esophageal dilator; tracheal bistour (a long, narrow surgical knife); tracheal dilator; tracheal hook; laryngeal injection set; laryngeal knife; laryngeal saw; laryngeal trocar; laryngectomy tube; adenoid curette; adenotome; metal tongue depressor; mouth gag; oral screw; salpingeal curette; tonsillectome; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tube; tonsil suturing hook; antom reforator; ethmoid curette; frontal sinus-rasp; nasal curette; nasal rasp; nasal rongeur; nasal saw; nasal scissors; nasal snare; sinus irrigator; sinus trephine; ear curette; ear excavator; ear rasp; ear scissor, ear snare; ear spoon; ear suction tube; malleous ripper; mastoid gauge; microsurgical ear chisel;

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				myringotomy tube inserter; ossici holding clamp; sacculotomy tack inserter; vein press; wire ear loop; microrule; mirror; mobilizer; ear, nose, and throat punch; ear, nose and throat knife; and ear, nose, and throat trocar.

Gastroenterology-Urology

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Gastroenterology -Urology	Blood Tubing Connectors	FKB	Connector, Blood Tubing, Infusion T	876.5820 Hemodialysis system and accessories. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer. (1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient.

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				(2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860). (3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860). (4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.
Gastroenterology -Urology	Catheters & Ports	LFK	Catheter, Femoral	876.5540 Blood access device and accessories. A blood access device and accessories is a device intended to provide access to a patient's blood for hemodialysis or other chronic uses. When used in hemodialysis,

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				it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices.
Gastroenterology -Urology	Dialysate Tubing	FID	Tubing, Dialysate	876.5820 Hemodialysis system and accessories. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer. (1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient. (2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the

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				semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860). (3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860). (4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.
Gastroenterology -Urology	Dialyzers	FJI	Dialyzer, Capillary, Hollow Fiber	876.5820 Hemodialysis system and accessories. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery

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				system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer. (1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient. (2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860). (3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the

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				dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860). (4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.
Gastroenterology -Urology	Dialyzers	KDI	Dialyzer, High Permeability With Or Without Sealed Dialysate System	876.5860 High permeability hemodialysis system. A high permeability hemodialysis system is a device intended for use as an artificial kidney system for the treatment of patients with renal failure, fluid overload, or toxemic conditions by performing such therapies as hemodialysis, hemofiltration, hemoconcentration, and hemodiafiltration. Using a hemodialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional hemodialysis system (§ 876.5820), the high permeability hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via a high ultrafiltration rate) and/or diffusion (via a concentration gradient in dialysate). During treatment, blood is circulated from the patient through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins

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				and/or fluid are transferred across the membrane from the blood to the dialysate compartment. The hemodialysis delivery machine controls and monitors the parameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. The high permeability hemodialysis system consists of the following devices: (1) The hemodialyzer consists of a semipermeable membrane with an in vitro ultrafiltration coefficient (Kuf) greater than 8 milliliters per hour per conventional millimeter of mercury, as measured with bovine or expired human blood, and is used with either an automated ultrafiltration controller or another method of ultrafiltration control to prevent fluid imbalance. (2) The hemodialysis delivery machine is similar to the extracorporeal blood system and dialysate delivery system of the hemodialysis system and accessories (§ 876.5820), with the addition of an ultrafiltration controller and mechanisms that monitor and/or control such parameters as fluid balance, dialysate composition, and patient treatment parameters (e.g., blood pressure, hematocrit, urea, etc.). (3) The high permeability hemodialysis system accessories include, but are not limited to, tubing lines and various treatment related monitors (e.g., dialysate pH, blood pressure, hematocrit, and blood recirculation monitors).
Gastroenterology -Urology	Endoscopes & Accessory Devices	KNS	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)	876.4300 Endoscopic electrosurgical unit and accessories. An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device includes the electrosurgical generator, patient plate, electric biopsy forceps,

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				electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, electrical clamp, self-opening rigid snare, flexible suction coagulator electrode, patient return wristlet, contact jelly, adaptor to the cord for transurethral surgical instruments, the electric cord for transurethral surgical instruments, and the transurethral desiccator.
Gastroenterology -Urology	Endoscopes & Accessory Devices	ODG	Endoscopic Ultrasound System, Gastroenterology-Urology	876.1500 Endoscope and accessories. An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binocular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have specialized uses in other medical specialty areas and that are covered by classification regulations

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				in other parts of the device classification regulations.
Gastroenterology -Urology	Extracorporeal Membrane Oxygenation (ECMO) Cannulas, System, and Blood Pump	LLB	System, Blood, Extracorporeal And Accessories	876.5820 Hemodialysis system and accessories. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer.
Gastroenterology -Urology	Gastrointestinal (GI) Stents	MQR	Stent, Colonic, Metallic, Expandable	878.3610 Esophageal prosthesis. An esophageal prosthesis is a rigid, flexible, or expandable tubular device made of a plastic, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the esophagus. The metal esophageal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.
Gastroenterology -Urology	Gastrointestinal (GI) Stents	MUM	Stent, Metallic, Expandable, Duodenal	878.3610 Esophageal prosthesis. An esophageal prosthesis is a rigid, flexible, or expandable tubular device made of a plastic, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the esophagus. The metal esophageal

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				prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.
Gastroenterology -Urology	Gastrointestinal (GI) Tubes	BSS	Tube, Nasogastric	876.5980 Gastrointestinal tube and accessories. A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use).
Gastroenterology -Urology	Gastrointestinal (GI) Tubes	FEG	Tube, Double Lumen For Intestinal Decompression And/Or Intubation	876.5980 Gastrointestinal tube and accessories. A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with

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				mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use).
Gastroenterology -Urology	Gastrointestinal (GI) Tubes	KNT	Tubes, Gastrointestinal (And Accessories)	876.5980 Gastrointestinal tube and accessories. A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use).
Gastroenterology -Urology	Gastrointestinal (GI) Tubes	PIF	Gastrointestinal Tubes With Enteral Specific Connectors	876.5980 Gastrointestinal tube and accessories. A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with

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				mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use).
Gastroenterology -Urology	Hemodialysis Catheter End Caps	PEH	Hemodialysis Catheter Luer End Cap	876.5540 Blood access device and accessories. A blood access device and accessories is a device intended to provide access to a patient's blood for hemodialysis or other chronic uses. When used in hemodialysis, it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices. (1) The implanted blood access device is a prescription device and consists of various flexible or rigid tubes, such as catheters, or cannulae, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes various catheters, shunts, and connectors specifically designed to provide access to blood. Examples include single and double lumen catheters with cuff(s), fully subcutaneous port-catheter systems, and A–V shunt cannulae (with vessel tips). The implanted blood access device may also contain coatings or additives which may provide additional functionality to the device. (2) The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis (§§ 870.3450 and 870.3460), and are intended to remain in the body for less than 30 days. This

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				generic type of device includes fistula needles, the single needle dialysis set (coaxial flow needle), and the single needle dialysis set (alternating flow needle). (3)Accessories common to either type include the shunt adaptor, cannula clamp, shunt connector, shunt stabilizer, vessel dilator, disconnect forceps, shunt guard, crimp plier, tube plier, crimp ring, joint ring, fistula adaptor, and declotting tray (including contents).
Gastroenterology -Urology	Hemodialysis Catheters	MPB	Catheter, Hemodialysis, Non-Implanted	876.5540 Blood access device and accessories. A blood access device and accessories is a device intended to provide access to a patient's blood for hemodialysis or other chronic uses. When used in hemodialysis, it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices. (1) The implanted blood access device is a prescription device and consists of various flexible or rigid tubes, such as catheters, or cannulae, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes various catheters, shunts, and connectors specifically designed to provide access to blood. Examples include single and double lumen catheters with cuff(s), fully subcutaneous port-catheter systems, and A–V shunt cannulae (with vessel tips). The implanted blood access device may also contain coatings or additives which may provide additional functionality to the device.

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				(2) The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis (§§ 870.3450 and 870.3460), and are intended to remain in the body for less than 30 days. This generic type of device includes fistula needles, the single needle dialysis set (coaxial flow needle), and the single needle dialysis set (alternating flow needle). (3)Accessories common to either type include the shunt adaptor, cannula clamp, shunt connector, shunt stabilizer, vessel dilator, disconnect forceps, shunt guard, crimp plier, tube plier, crimp ring, joint ring, fistula adaptor, and declotting tray (including contents).
Gastroenterology -Urology	Hemodialysis Catheters	MSD	Catheter, Hemodialysis, Implanted	876.5540 Blood access device and accessories. A blood access device and accessories is a device intended to provide access to a patient's blood for hemodialysis or other chronic uses. When used in hemodialysis, it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices. (1) The implanted blood access device is a prescription device and consists of various flexible or rigid tubes, such as catheters, or cannulae, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes various catheters, shunts, and connectors specifically designed to provide access to blood. Examples

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				include single and double lumen catheters with cuff(s), fully subcutaneous port-catheter systems, and A–V shunt cannulae (with vessel tips). The implanted blood access device may also contain coatings or additives which may provide additional functionality to the device. (2) The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis (§§ 870.3450 and 870.3460), and are intended to remain in the body for less than 30 days. This generic type of device includes fistula needles, the single needle dialysis set (coaxial flow needle), and the single needle dialysis set (alternating flow needle). (3)Accessories common to either type include the shunt adaptor, cannula clamp, shunt connector, shunt stabilizer, vessel dilator, disconnect forceps, shunt guard, crimp plier, tube plier, crimp ring, joint ring, fistula adaptor, and declotting tray (including contents).
Gastroenterology -Urology	Hemodialysis Circuit Accessories	KOC	Accessories, Blood Circuit, Hemodialysis	876.5820 Hemodialysis system and accessories. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the

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				blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer. (1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient. (2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860). (3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or

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				the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860). (4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.
Gastroenterology -Urology	Hemodialysis Dialysate	KPO	Dialysate Concentrate For Hemodialysis (Liquid Or Powder)	876.5820 Hemodialysis system and accessories. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer. (1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient. (2) The conventional dialyzer allows a transfer of water and solutes between

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				the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860). (3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860). (4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.
Gastroenterology -Urology	Hemodialysis Dialysate Delivery Systems	FIL	System, Dialysate Delivery, Single Pass	876.5820 Hemodialysis system and accessories. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a

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				conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer. (1)Click to open paragraph tools The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient. (2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860). (3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate

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				compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860). (4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.
Gastroenterology -Urology	Hemodialysis Dialysate Delivery Systems	FKP	System, Dialysate Delivery, Single Patient	876.5820 Hemodialysis system and accessories. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the

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				dialysate compartment of the dialyzer. (1)Click to open paragraph tools The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient. (2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860). (3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860). (4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale,

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.
Gastroenterology -Urology	Kidney Perfusion Systems	KDN	System, Perfusion, Kidney	876.5880 Isolated kidney perfusion and transport system and accessories. An isolated kidney perfusion and transport system and accessories is a device that is used to support a donated or a cadaver kidney and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient. This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus with or without oxygenator, and disposable perfusion set.
Gastroenterology -Urology	Ligators	MND	Ligator, Esophageal	876.4400 Hemorrhoidal ligator. A hemorrhoidal ligator is a device used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or band placed around the hemorrhoid.
Gastroenterology -Urology	Peritoneal Dialysate Delivery Systems	KPF	System, Dialysate Delivery, Semi-Automatic, Peritoneal	876.5630 Peritoneal dialysis system and accessories. (1) A peritoneal dialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a peritoneal access device, an administration set for peritoneal dialysis, a source of dialysate, and, in some cases, a water purification mechanism. After the dialysate is instilled into the patient's peritoneal cavity, it is allowed to dwell there so that undesirable substances from the patient's blood pass through the lining membrane of the peritoneal cavity into this dialysate. These substances are then removed when the dialysate is drained from the patient. The peritoneal dialysis system may regulate and monitor the dialysate temperature,

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used. This generic device includes the semiautomatic and the automatic peritoneal delivery system. (2) The peritoneal access device is a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritoneal catheter, intended to remain in the peritoneal cavity for less than 30 days, or a long term peritoneal catheter. Accessories include stylets and trocars to aid in the insertion of the catheter and an obturator to maintain the patency of the surgical fistula in the abdominal wall between treatments. (3) The disposable administration set for peritoneal dialysis consists of tubing, an optional reservoir bag, and appropriate connectors. It may include a peritoneal dialysate filter to trap and remove contaminating particles. (4) The source of dialysate may be sterile prepackaged dialysate (for semiautomatic peritoneal dialysate delivery systems or "cycler systems") or dialysate prepared from dialysate concentrate and sterile purified water (for automatic peritoneal dialysate delivery systems or "reverse osmosis" systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.
Gastroenterology -Urology	Peritoneal Dialysis Catheters	FJS	Catheter, Peritoneal, Long-Term Indwelling	876.5630 Peritoneal dialysis system and accessories. (1) A peritoneal dialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				peritoneal access device, an administration set for peritoneal dialysis, a source of dialysate, and, in some cases, a water purification mechanism. After the dialysate is instilled into the patient's peritoneal cavity, it is allowed to dwell there so that undesirable substances from the patient's blood pass through the lining membrane of the peritoneal cavity into this dialysate. These substances are then removed when the dialysate is drained from the patient. The peritoneal dialysis system may regulate and monitor the dialysate temperature, volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used. This generic device includes the semiautomatic and the automatic peritoneal delivery system. (2) The peritoneal access device is a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritoneal catheter, intended to remain in the peritoneal cavity for less than 30 days, or a long term peritoneal catheter. Accessories include stylets and trocars to aid in the insertion of the catheter and an obturator to maintain the patency of the surgical fistula in the abdominal wall between treatments. (3) The disposable administration set for peritoneal dialysis consists of tubing, an optional reservoir bag, and appropriate connectors. It may include a peritoneal dialysate filter to trap and remove contaminating particles. (4) The source of dialysate may be sterile prepackaged dialysate (for semiautomatic peritoneal dialysate delivery systems or “cycler systems”) or dialysate prepared from dialysate

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				concentrate and sterile purified water (for automatic peritoneal dialysate delivery systems or “reverse osmosis” systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.
Gastroenterology -Urology	Peritoneal Dialysis Catheters	FKO	Catheter, Peritoneal Dialysis, Single Use	876.5630 Peritoneal dialysis system and accessories. (1) A peritoneal dialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a peritoneal access device, an administration set for peritoneal dialysis, a source of dialysate, and, in some cases, a water purification mechanism. After the dialysate is instilled into the patient's peritoneal cavity, it is allowed to dwell there so that undesirable substances from the patient's blood pass through the lining membrane of the peritoneal cavity into this dialysate. These substances are then removed when the dialysate is drained from the patient. The peritoneal dialysis system may regulate and monitor the dialysate temperature, volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used. This generic device includes the semiautomatic and the automatic peritoneal delivery system. (2) The peritoneal access device is a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritoneal catheter, intended to remain in the peritoneal cavity for less than 30 days, or a long term peritoneal catheter. Accessories include stylets and trocars to aid in the insertion of the catheter and an

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				obturator to maintain the patency of the surgical fistula in the abdominal wall between treatments. (3) The disposable administration set for peritoneal dialysis consists of tubing, an optional reservoir bag, and appropriate connectors. It may include a peritoneal dialysate filter to trap and remove contaminating particles. (4) The source of dialysate may be sterile prepackaged dialysate (for semiautomatic peritoneal dialysate delivery systems or "cycler systems") or dialysate prepared from dialysate concentrate and sterile purified water (for automatic peritoneal dialysate delivery systems or "reverse osmosis" systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.
Gastroenterology -Urology	Transfusion and Plasmapheresis Devices	LKN	Separator, Automated, Blood Cell And Plasma, Therapeutic	[No CFR Description or FDA Product Classification Database definition.]
Gastroenterology -Urology	Urinary Catheters and Related Devices	EZL	Catheter, Retention Type, Balloon	876.5130 Urological catheter and accessories. A urological catheter and accessories is a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract. This generic type of device includes radiopaque urological catheters, ureteral catheters, urethral catheters, coudé catheters, balloon retention type catheters, straight catheters, upper urinary tract catheters, double lumen female urethrographic catheters, disposable ureteral catheters, male urethrographic catheters, and urological catheter accessories including ureteral catheter stylets, ureteral catheter adapters, ureteral catheter holders, ureteral catheter stylets, ureteral catheterization trays, and the gastro-

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				urological irrigation tray (for urological use).
Gastroenterology -Urology	Urinary Catheters and Related Devices	FCN	Urinary Drainage Collection Kit, For Indwelling Catheter	876.5250 Urine collector and accessories. A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection. The two kinds of urine collectors are: (1) A urine collector and accessories intended to be connected to an indwelling catheter, which includes the urinary drainage collection kit and the closed urine drainage system and drainage bag; and (2)A urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device, and the paste-on device for incontinence.

General and Plastic Surgery

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
General and Plastic Surgery	Aspiration Pumps	BTA	Pump, Portable, Aspiration (Manual Or Powered)	878.4780 Powered suction pump. A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter.
General and Plastic Surgery	Cautery Devices	GEI	Electrosurgical, Cutting & Coagulation & Accessories	878.4400 Electrosurgical cutting and coagulation device and accessories. An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				control bleeding by use of high-frequency electrical current.
General and Plastic Surgery	Cerebrospinal Fluid (CSF) Shunts and Drains	GBS	Catheter, Ventricular, General & Plastic Surgery	878.4200 Introduction/drainage catheter and accessories. An introduction/drainage catheter is a device that is a flexible single or multilumen tube intended to be used to introduce nondrug fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions. Examples include irrigation and drainage catheters, pediatric catheters, peritoneal catheters (including dialysis), and other general surgical catheters. An introduction/drainage catheter accessory is intended to aid in the manipulation of or insertion of the device into the body. Examples of accessories include adaptors, connectors, and catheter needles.
General and Plastic Surgery	Clip Appliers	GDO	Applier, Surgical, Clip	878.4800 Manual surgical instrument for general use. A manual surgical instrument for general use is a nonpowered, hand-held, or hand manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape,

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892 of this chapter.
General and Plastic Surgery	Clip Appliers	HBT	Applier, Hemostatic Clip	878.4800 Manual surgical instrument for general use. A manual surgical instrument for general use is a nonpowered, hand-held, or hand manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892 of this chapter.
General and Plastic Surgery	Clips	MCH	Clip, Hemostatic	878.4300 Implantable clip. An implantable clip is a clip-like device intended to connect internal tissues to aid healing. It is not absorbable.
General and Plastic Surgery	Gauze/Sponge	NAB	Gauze/Sponge, Nonresorbable For External Use	878.4014 Nonresorbable gauze/sponge for external use. A nonresorbable gauze/sponge for external use is a sterile or nonsterile device intended for medical purposes, such as to be placed directly on a patient's wound to absorb exudate. It

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				consists of a strip, piece, or pad made from open woven or nonwoven mesh cotton cellulose or a simple chemical derivative of cellulose. This classification does not include a nonresorbable gauze/sponge for external use that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.
General and Plastic Surgery	Hemostatic Agents	LMF	Agent, Absorbable Hemostatic, Collagen Based	878.4490 Absorbable hemostatic agent and dressing. An absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable.
General and Plastic Surgery	Hemostatic Agents	PMX	Absorbable Collagen Hemostatic Agent With Thrombin	878.4490 Absorbable hemostatic agent and dressing. An absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable.
General and Plastic Surgery	Lancets	FMK	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature	878.4850 Blood lancets. A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base (including an integral sharps injury prevention feature) that is used to puncture the skin to obtain a drop of blood for diagnostic purposes. The integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use.
General and Plastic Surgery	Surgical Drapes	PUI	Drape, Surgical, Exempt	878.4370 Surgical drape and drape accessories. A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The device includes a plastic wound protector that may adhere to the skin around a surgical incision or be placed in a wound to cover its exposed edges, and a latex

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				drape with a self-retaining finger cot that is intended to allow repeated insertion of the surgeon's finger into the rectum during performance of a transurethral prostatectomy.
General and Plastic Surgery	Sutures	GAM	Suture, Absorbable, Synthetic, Polyglycolic Acid	878.4493 Absorbable poly(glycolide/l-lactide) surgical suture. An absorbable poly(glycolide/l-lactide) surgical suture (PGL suture) is an absorbable sterile, flexible strand as prepared and synthesized from homopolymers of glycolide and copolymers made from 90 percent glycolide and 10 percent l-lactide, and is indicated for use in soft tissue approximation. A PGL suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. "Monograph for Absorbable Surgical Sutures;" it may be monofilament or multifilament (braided) in form; it may be uncoated or coated; and it may be undyed or dyed with an FDA-approved color additive. Also, the suture may be provided with or without a standard needle attached.
General and Plastic Surgery	Sutures	GAP	Suture, Nonabsorbable, Silk	878.5030 Natural nonabsorbable silk surgical suture. Natural nonabsorbable silk surgical suture is a nonabsorbable, sterile, flexible multifilament thread composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. Natural nonabsorbable silk surgical suture is indicated for use in soft tissue approximation. Natural nonabsorbable silk surgical suture meets the United States Pharmacopeia (U.S.P.) monograph requirements for Nonabsorbable Surgical Suture (class I). Natural nonabsorbable silk surgical suture may be braided or twisted; it may be provided uncoated or coated; and it may be undyed or dyed with an FDA listed color additive.

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
General and Plastic Surgery	Tape and Adhesive Bandages	KGX	Tape And Bandage, Adhesive	880.5240 Medical adhesive tape and adhesive bandage. A medical adhesive tape or adhesive bandage is a device intended for medical purposes that consists of a strip of fabric material or plastic, coated on one side with an adhesive, and may include a pad of surgical dressing without a disinfectant. The device is used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin.
General and Plastic Surgery	Tourniquets	GAX	Tourniquet, Nonpneumatic	878.5900 Nonpneumatic tourniquet. A nonpneumatic tourniquet is a device consisting of a strap or tubing intended to be wrapped around a patient's limb and tightened to reduce circulation.
General and Plastic Surgery	Wound Dressings	FRO	Dressing, Wound, Drug	[No CFR Description or FDA Product Classification Database definition.]
General and Plastic Surgery	Wound Dressings	MGR	Dressing, Wound And Burn, Interactive	[No CFR Description or FDA Product Classification Database definition.]
General and Plastic Surgery	Wound Dressings	NAC	Dressing, Wound, Hydrophilic	878.4018 Hydrophilic wound dressing. A hydrophilic wound dressing is a sterile or non-sterile device intended to cover a wound and to absorb exudate. It consists of nonresorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon). This classification does not include a hydrophilic wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.
General and Plastic Surgery	Wound Dressings	NAD	Dressing, Wound, Occlusive	878.4020 Occlusive wound dressing. An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				adhesive backing. This classification does not include an occlusive wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

General Hospital

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
General Hospital	Breathing System Collection Devices	CBD	Bottle, Collection, Breathing System (Calibrated)	880.6740 Vacuum-powered body fluid suction apparatus. A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).
General Hospital	Catheters & Ports	FOS	Catheter, Umbilical Artery	880.5200 Intravascular catheter. An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be constructed of metal, rubber, plastic, or a combination of these materials.
General Hospital	Catheters & Ports	FOZ	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	880.5200 Intravascular catheter. An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				constructed of metal, rubber, plastic, or a combination of these materials.
General Hospital	Catheters & Ports	LJT	Port & Catheter, Implanted, Subcutaneous, Intravascular	880.5965 Subcutaneous, implanted, intravascular infusion port and catheter. A subcutaneous, implanted, intravascular infusion port and catheter is a device that consists of a subcutaneous, implanted reservoir that connects to a long-term intravascular catheter. The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood. The device consists of a portal body with a resealable septum and outlet made of metal, plastic, or combination of these materials and a long-term intravascular catheter is either preattached to the port or attached to the port at the time of device placement. The device is available in various profiles and sizes and can be of a single or multiple lumen design.
General Hospital	Catheters & Ports	PND	Midline Catheter	880.5200 Intravascular catheter. An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be constructed of metal, rubber, plastic, or a combination of these materials.
General Hospital	Disinfection & Pasteurization	LDS	Device, Pasteurization, Hot Water	880.6991 Medical washer. A medical washer is a device that is intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.
General Hospital	Disinfection & Pasteurization	LRJ	Disinfectant, Medical Devices	880.6890 General purpose disinfectants. A general purpose disinfectant is a germicide intended to process noncritical medical devices and equipment surfaces. A general purpose disinfectant can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				disinfection. Noncritical medical devices make only topical contact with intact skin.
General Hospital	Disinfection & Pasteurization	MEC	Disinfector, Medical Devices	880.6992 Medical washer-disinfector. A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices. (1) Medical washer-disinfectors that are intended to clean, high level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices. (2) Medical washer-disinfectors that are intended to clean, low or intermediate level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.
General Hospital	Disinfection & Pasteurization	PSW	High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Liquid	892.1570 Diagnostic ultrasonic transducer. A diagnostic ultrasonic transducer is a device made of a piezoelectric material that converts electrical signals into acoustic signals and acoustic signals into electrical signals and intended for use in diagnostic ultrasonic medical devices. Accessories of this generic type of device may include transmission media for acoustically coupling the transducer to the body surface, such as acoustic gel, paste, or a flexible fluid container.
General Hospital	Endoscopes & Accessory Devices	FEB	Accessories, Cleaning, For Endoscope	876.1500 Endoscope and accessories. An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binocular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.
General Hospital	Enteral Infusion Pumps	LZH	Pump, Infusion, Enteral	880.5725 Infusion pump. An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.
General Hospital	Filters	CAH	Filter, Bacterial, Breathing-Circuit	868.5260 Breathing circuit bacterial filter. A breathing circuit bacterial filter is a device that is intended to remove

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				microbiological and particulate matter from the gases in the breathing circuit.
General Hospital	Fluid Warmers	LGZ	Warmer, Thermal, Infusion Fluid	880.5725 Infusion pump. An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.
General Hospital	Infant Warming Devices	FMT	Warmer, Infant Radiant	880.5130 Infant radiant warmer. The infant radiant warmer is a device consisting of an infrared heating element intended to be placed over an infant to maintain the infant's body temperature by means of radiant heat. The device may also contain a temperature monitoring sensor, a heat output control mechanism, and an alarm system (infant temperature, manual mode if present, and failure alarms) to alert operators of a temperature condition over or under the set temperature, manual mode time limits, and device component failure, respectively. The device may be placed over a pediatric hospital bed or it may be built into the bed as a complete unit.
General Hospital	Infusion Filters	FPB	Filter, Infusion Line	880.5440 Intravascular administration set. An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.
General Hospital	Infusion Pumps	FRN	Pump, Infusion	880.5725 Infusion pump. An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.
General Hospital	Intravenous (IV) Containers	KPE	Container, I.V.	880.5025 I.V. container. An I.V. container is a container made of plastic or glass used to hold a fluid mixture to be administered to a patient through an intravascular administration set.
General Hospital	Intravenous (IV) Stopcocks	FMG	Stopcock, I.V. Set	880.5440 Intravascular administration set. An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.
General Hospital	Needles	FMI	Needle, Hypodermic, Single Lumen	880.5570 Hypodermic single lumen needle. A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.
General Hospital	Needles	PTI	Non-Coring (Huber) Needle	880.5570 Hypodermic single lumen needle. A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.
General Hospital	Needles	QNS	Low Dead Space Needle, Single Lumen, Hypodermic	880.5570 Hypodermic single lumen needle. A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.
General Hospital	Non-Sterile Personal Protective Equipment (PPE)	FXX	Mask, Surgical	878.4040 Surgical apparel. Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns.
General Hospital	Non-Sterile Personal Protective Equipment (PPE)	FYC	Gown, Isolation, Surgical	878.4040 Surgical apparel. Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.
General Hospital	Non-Sterile Personal Protective Equipment (PPE)	LYY	Latex Patient Examination Glove	880.6250 Non-powdered patient examination glove. A non-powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.
General Hospital	Non-Sterile Personal Protective Equipment (PPE)	LYZ	Vinyl Patient Examination Glove	880.6250 Non-powdered patient examination glove. A non-powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.
General Hospital	Non-Sterile Personal Protective Equipment (PPE)	LZA	Polymer Patient Examination Glove	880.6250 Non-powdered patient examination glove. A non-powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
General Hospital	Non-Sterile Personal Protective Equipment (PPE)	MSH	Respirator, Surgical	878.4040 Surgical apparel. Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns.
General Hospital	Operating Room (OR) Suction Apparatus	GCX	Apparatus, Suction, Operating-Room, Wall Vacuum Powered	880.6740 Vacuum-powered body fluid suction apparatus. A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).
General Hospital	Public Use Respirators	NZJ	Respirator, N95, For Use By The General Public In Public Health Medical Emergencies	880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies. A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.
General Hospital	Specimen Collection Devices	FMH	Container, Specimen, Sterile	864.3250 Specimen transport and storage container. A specimen transport and storage container, which may be empty or prefilled, is a device intended to contain biological specimens, body waste, or

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				body exudate during storage and transport in order that the matter contained therein can be destroyed or used effectively for diagnostic examination. If prefilled, the device contains a fixative solution or other general purpose reagent to preserve the condition of a biological specimen added to the container. This section does not apply to specimen transport and storage containers that are intended for use as part of an over-the-counter test sample collection system for drugs of abuse testing.
General Hospital	Specimen Collection Devices	KDQ	Bottle, Collection, Vacuum	880.6740 Vacuum-powered body fluid suction apparatus. A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).
General Hospital	Spinal Catheters	MAJ	Catheter, Percutaneous, Intraspinal, Short Term	868.5120 Anesthesia conduction catheter. An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia.
General Hospital	Sterilization	FLE	Sterilizer, Steam	880.6880 Steam sterilizer. A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical products by means of pressurized steam.
General Hospital	Sterilization	FLF	Sterilizer, Ethylene-Oxide Gas	880.6860 Ethylene oxide gas sterilizer. An ethylene gas sterilizer is a nonportable device intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical products.
General Hospital	Sterilization	FRG	Wrap, Sterilization	880.6850 Sterilization wrap. A sterilization wrap (pack, sterilization wrapper, bag, or accessories, is a device

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.
General Hospital	Sterilization	KMH	Sterilizer, Dry Heat	880.6870 Dry-heat sterilizer. A dry-heat sterilizer is a device that is intended for use by a health care provider to sterilize medical products by means of dry heat.
General Hospital	Sterilization	MED	Sterilant, Medical Devices	880.6885 Liquid chemical sterilants/high level disinfectants. A liquid chemical sterilant/high level disinfectant is a germicide that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use. Critical devices make contact with normally sterile tissue or body spaces during use. Semicritical devices make contact during use with mucous membranes or nonintact skin.
General Hospital	Sterilization	MLR	Sterilizer, Chemical	880.6860 Ethylene oxide gas sterilizer. An ethylene gas sterilizer is a nonportable device intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical products.
General Hospital	Stretchers	FPO	Stretcher, Wheeled	880.6910 Wheeled stretcher. A wheeled stretcher is a device consisting of a platform mounted on a wheeled frame that is designed to transport patients in a horizontal position. The device may have side rails, supports for fluid infusion equipment, and patient securement straps. The frame may be fixed or collapsible for use in an ambulance.
General Hospital	Suction Catheters	JOL	Catheter And Tip, Suction	880.6740 Vacuum-powered body fluid suction apparatus. A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).
General Hospital	Suction Tubes and Catheters	BYY	Tube, Aspirating, Flexible, Connecting	880.6740 Vacuum-powered body fluid suction apparatus. A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).
General Hospital	Surgical Personal Protective Equipment (PPE)	FYA	Gown, Surgical	878.4040 Surgical apparel. Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.
General Hospital	Surgical Personal Protective Equipment (PPE)	KGO	Surgeon's Gloves	878.4460 Non-powdered surgeon's glove. A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.
General Hospital	Syringes	FMF	Syringe, Piston	880.5860 Piston syringe. A piston syringe is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body.
General Hospital	Syringes	MEG	Syringe, Antistick	880.5860 Piston syringe. A piston syringe is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body.
General Hospital	Syringes	QNQ	Low Dead Space Piston Syringe	880.5860 Piston syringe. A piston syringe is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body.
General Hospital	Thermoregulatory Monitors	FLL	Thermometer, Electronic, Clinical	880.2910 Clinical electronic thermometer. A clinical electronic thermometer is a device used to measure the body temperature of a patient by means of a transducer coupled with an electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.
General Hospital	Tubing	FPK	Tubing, Fluid Delivery	880.5440 Intravascular administration set. An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

Hematology and Pathology

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Hematology and Pathology	Coagulation Tests	GFO	Activated Partial Thromboplastin	864.7925 Partial thromboplastin time tests. A partial thromboplastin time test is a device used for primary screening for coagulation abnormalities, for evaluation of the effect of therapy on procoagulant disorders, and as an assay for coagulation factor deficiencies of the intrinsic coagulation pathway.
Hematology and Pathology	Coagulation Tests	GGW	Test, Time, Partial Thromboplastin	864.7925 Partial thromboplastin time tests. A partial thromboplastin time test is a device used for primary screening for coagulation abnormalities, for evaluation of the effect of therapy on procoagulant disorders, and as an assay for coagulation factor deficiencies of the intrinsic coagulation pathway.
Hematology and Pathology	Coagulation Tests	JBP	Activated Whole Blood Clotting Time	864.7140 Activated whole blood clotting time tests. An activated whole blood clotting time tests is a device, used to monitor heparin therapy for the treatment of venous thrombosis or pulmonary embolism by measuring the coagulation time of whole blood.
Hematology and Pathology	Specimen Collection Devices	KDW	Container, Specimen Mailer And Storage, Temperature Controlled, Sterile	864.3250 Specimen transport and storage container. A specimen transport and storage container, which may be empty or prefilled, is a device intended to contain biological specimens, body waste, or body exudate during storage and transport in order that the matter

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				contained therein can be destroyed or used effectively for diagnostic examination. If prefilled, the device contains a fixative solution or other general purpose reagent to preserve the condition of a biological specimen added to the container. This section does not apply to specimen transport and storage containers that are intended for use as part of an over-the-counter test sample collection system for drugs of abuse testing.

Immunology and Microbiology

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Immunology and Microbiology	Antimicrobial Testing Devices	JTN	Susceptibility Test Discus, Antimicrobial	866.1620 Antimicrobial susceptibility test disc. An antimicrobial susceptibility test disc is a device that consists of antimicrobic-impregnated paper discs used to measure by a disc-agar diffusion technique or a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial agents. In the disc-agar diffusion technique, bacterial susceptibility is ascertained by directly measuring the magnitude of a zone of bacterial inhibition around the disc on an agar surface. The disc-broth elution technique is associated with an automated rapid susceptibility test system and employs a fluid medium in which susceptibility is ascertained by photometrically measuring changes in bacterial growth resulting when antimicrobial material is eluted from the disc into the fluid medium. Test results are used to determine the antimicrobial agent of choice in the treatment of bacterial diseases.
Immunology and Microbiology	Antimicrobial Testing Devices	JTO	Discs, Strips, And Reagents,	866.2660 Microorganism differentiation and identification device.

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
			Microorganism Differentiation	A microorganism differentiation and identification device is a device intended for medical purposes that consists of one or more components, such as differential culture media, biochemical reagents, and paper discs or paper strips impregnated with test reagents, that are usually contained in individual compartments and used to differentiate and identify selected microorganisms. The device aids in the diagnosis of disease.
Immunology and Microbiology	Media Culture	JTZ	Culture Media, Antimicrobial Susceptibility Test, Mueller Hinton Agar/Broth	866.1700 Culture medium for antimicrobial susceptibility tests. A culture medium for antimicrobial susceptibility tests is a device intended for medical purposes that consists of any medium capable of supporting the growth of many of the bacterial pathogens that are subject to antimicrobial susceptibility tests. The medium should be free of components known to be antagonistic to the common agents for which susceptibility tests are performed in the treatment of disease.
Immunology and Microbiology	Transport Medium	JSM	Culture Media, Non-Propagating Transport	866.2390 Transport culture medium. A transport culture medium is a device that consists of a semisolid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

Neurology

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Neurology	Cerebrospinal Fluid (CSF) Shunts and Drains	JXG	Shunt, Central Nervous System And Components	882.5550 Central nervous system fluid shunt and components. A central nervous system fluid shunt is a device or combination of devices used to

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catheters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.
Neurology	Dural Substitutes	GXQ	Dura Substitute	882.5910 Dura substitute. A dura substitute is a sheet or material that is used to repair the dura mater (the membrane surrounding the brain).
Neurology	Dural Substitutes	NQR	Sealant, Dural	[No CFR Description; definition provided from FDA Product Classification Database] Dural sealants are devices intended to aid in preventing cerebrospinal fluid leakage through suture-approximated dural wound edges. The sealant is sprayed or layered onto sutured dural wound edges and allowed to polymerize in place.
Neurology	Intracranial Pressure Monitors	GWM	Device, Monitoring, Intracranial Pressure	882.1620 Intracranial pressure monitoring device. An intracranial pressure monitoring device is a device used for short-term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.
Neurology	Neurosurgical Instruments	HAO	Instrument, Surgical, Non-Powered	882.4535 Nonpowered neurosurgical instrument. A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Neurology	Neurosurgical Instruments	HBE	Drills, Burrs, Trephines & Accessories (Simple, Powered)	882.4310 Powered simple cranial drills, burrs, trephines, and their accessories. Powered simple cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments are used with a power source but do not have a clutch mechanism to disengage the tip after penetrating the skull.
Neurology	Neurosurgical Instruments	HBL	Holder, Head, Neurosurgical (Skull Clamp)	882.4460 Neurosurgical head holder (skull clamp). A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures.
Neurology	Neurosurgical Instruments	HCH	Clip, Aneurysm	882.5200 Aneurysm clip. An aneurysm clip is a device used to occlude an intracranial aneurysm (a balloon-like sac formed on a blood vessel) to prevent it from bleeding or bursting.
Neurology	Neurosurgical Instruments	HCI	Applier, Aneurysm Clip	882.4175 Aneurysm clip applier. An aneurysm clip applier is a device used by the surgeon for holding and applying intracranial aneurysm clips.
Neurology	Neurovascular Embolization Devices	HCG	Device, Neurovascular Embolization	882.5950 Neurovascular embolization device. A neurovascular embolization device is an intravascular implant intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation.
Neurology	Oximeters	QEM	Cerebral Oximeter	870.2700 Oximeter. An oximeter is a device used to transmit radiation at a known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.
Neurology	Thrombus Retriever Catheters	NRY	Catheter, Thrombus Retriever	870.1250 Percutaneous catheter. A percutaneous catheter is a device that is introduced into a vein or artery

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
				through the skin using a dilator and a sheath (introducer) or guide wire.
Neurology	Tissue Adhesive for Embolization	KGG	Tissue Adhesive For Use In Embolization Of Brain Arteriovenous Malformations	[No CFR Description or FDA Product Classification Database definition.]

Obstetrics and Gynecology

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Obstetrics and Gynecology	Fetal Bladder Stents	MPR	Stent, Bladder, Fetal	[No CFR Description or FDA Product Classification Database definition.]
Obstetrics and Gynecology	Fetal Monitors	HGM	System, Monitoring, Perinatal	884.2740 Perinatal monitoring system and accessories. A perinatal monitoring system is a device used to show graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating uterine contraction and fetal heart monitors with appropriate displays of the well-being of the fetus during pregnancy, labor, and delivery. This generic type of device may include any of the devices subject to §§ 884.2600, 884.2640, 884.2660, 884.2675, 884.2700, and 884.2720. This generic type of device may include the following accessories: Central monitoring system and remote repeaters, signal analysis and display equipment, patient and equipment supports, and component parts.
Obstetrics and Gynecology	Intrauterine Tamponade Balloon	OQY	Intrauterine Tamponade Balloon	884.4530 Obstetric-gynecologic specialized manual instrument. An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance.

Orthopedic

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Orthopedic	Neurosurgical Instruments	MAX	Intervertebral Fusion Device With Bone Graft, Lumbar	888.3080 Intervertebral body fusion device. An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.
Orthopedic	Neurosurgical Instruments	NKB	Thoracolumbosacral Pedicle Screw System	888.3070 Thoracolumbosacral pedicle screw system. (1) Rigid pedicle screw systems are comprised of multiple components, made from a variety of materials that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of screws, longitudinal members (e.g., plates, rods including dual diameter rods, plate/rod combinations), transverse or cross connectors, and interconnection mechanisms (e.g., rod-to-rod connectors, offset connectors).
Orthopedic	Neurosurgical Instruments	ODP	Intervertebral Fusion Device With Bone Graft, Cervical	888.3080 Intervertebral body fusion device. An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

Physical Medicine

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Physical Medicine	Orthoses	IQF	Orthosis, Cervical-Thoracic, Rigid	890.3490 Truncal orthosis. A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of truncal orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.
Physical Medicine	Orthoses	IQK	Orthosis, Cervical	890.3490 Truncal orthosis. A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of truncal orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.

Radiology

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Radiology	Computed Tomography (CT) Scan	JAK	System, X-Ray, Tomography, Computed	892.1750 Computed tomography x-ray system. A computed tomography x-ray system is a diagnostic x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
Radiology	Plain X-ray Systems	IZL	System, X-Ray, Mobile	892.1720 Mobile x-ray system. A mobile x-ray system is a transportable device system intended to be used to generate and control x-ray for diagnostic procedures. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
Radiology	Plain X-ray Systems	KPR	System, X-Ray, Stationary	892.1680 Stationary x-ray system. A stationary x-ray system is a permanently installed diagnostic system intended to generate and control x-rays for examination of various anatomical regions. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
Radiology	Ultrasound Systems and Accessory Devices	ITX	Transducer, Ultrasonic, Diagnostic	892.1570 Diagnostic ultrasonic transducer. A diagnostic ultrasonic transducer is a device made of a piezoelectric material that converts electrical signals into acoustic signals and acoustic signals into electrical signals and intended for use in diagnostic ultrasonic medical devices. Accessories of this generic type of device may include transmission media for acoustically coupling the transducer to the body surface, such as acoustic gel, paste, or a flexible fluid container.

Medical Specialty Panel	Device Type	Product Code	Product Code Preferred Name	21 CFR Description
Radiology	Ultrasound Systems and Accessory Devices	IYN	System, Imaging, Pulsed Doppler, Ultrasonic	892.1550 Ultrasonic pulsed doppler imaging system. An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
Radiology	Ultrasound Systems and Accessory Devices	IYO	System, Imaging, Pulsed Echo, Ultrasonic	892.1560 Ultrasonic pulsed echo imaging system. An ultrasonic pulsed echo imaging system is a device intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
Radiology	Ultrasound Systems and Accessory Devices	MUI	Media, Coupling, Ultrasound	892.1570 Diagnostic ultrasonic transducer. A diagnostic ultrasonic transducer is a device made of a piezoelectric material that converts electrical signals into acoustic signals and acoustic signals into electrical signals and intended for use in diagnostic ultrasonic medical devices. Accessories of this generic type of device may include transmission media for acoustically coupling the transducer to the body surface, such as acoustic gel, paste, or a flexible fluid container.