FDA Executive Summary

Prepared for the
February 6, 2024, meeting of the
General Hospital and Personal Use Devices Panel of the
Medical Devices Advisory Committee

General Issues Panel
Medical Device Supply Chain Resiliency and Shortages & Proposed 506J Device List

Discussion on Medical Device Supply Chain Resiliency and Shortage Issues, including the Proposed 506J Device List

Contents

i. List of Acronyms and Abbreviations

CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CMDL	Critical Medical Device List
COVID-19	Coronavirus Disease 2019
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FY	Fiscal Year
PHE	Public Health Emergency

ii. Introduction, Purpose, and Structure of the Panel Meeting

The Food and Drug Administration (FDA) plays a critical role in promoting resiliency and protecting the supply chains of critical medical devices needed to deliver healthcare and protect public health during public health emergencies (PHEs). Resilient medical device supply chains are a foundational element of a strong national emergency preparedness and response strategy.

In recognition of the FDA's role in supply chain resiliency and shortage prevention, in March 2020, Congress gave the FDA for the first time, authority related to medical device shortages (section 506J of the Federal Food, Drug, and Cosmetic [FD&C] Act).

Section 506J requires manufacturers to notify the FDA during, or in advance of, a PHE of a permanent discontinuance in the manufacture of certain devices, or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in the domestic supply of that device; and the reasons for such discontinuance and/or interruption.

Section 2514 of the Consolidated Appropriations Act, 2023 (H.R. 2617, "Fiscal Year (FY) 2023 Omnibus"), enacted in December 2022, amended the Coronavirus Aid, Relief, and Economic Security (CARES) Act authorities by requiring the FDA to issue or revise guidance regarding requirements under section 506J, to facilitate voluntary notifications, and to include a list of device product codes for which a manufacturer of such device is required to notify the FDA in accordance with section 506J (hereafter referred to the 506J Device List).

The FDA is convening this General Hospital and Personal Use Devices Panel (the Panel) of the Medical Devices Advisory Committee meeting on February 6, 2024, to discuss and make recommendations on medical device supply chain resiliency and shortage issues, including the proposed 506J Device List. This meeting will also fulfill, in part, section

3302 of the FY 2023 Omnibus which directs the FDA to convene one or more panels of the Medical Devices Advisory Committee not less than once per year for the purpose of providing advice to the Secretary on topics related to medical devices used in pandemic preparedness and response.

The panel meeting will be held in in person over the course of one day and includes time for the FDA and external stakeholder presentations, open public comment, questions by the Panel and deliberation. There will be a virtual option for attendees.

a. Purpose and Structure of the Meeting

The General Hospital and Personal Use Devices Panel (the Panel) of the Medical Devices Advisory Committee will convene on February 6, 2024, to discuss and make recommendations on medical device supply chain resiliency and shortage issues, including the proposed 506J Device List.

The Panel will discuss and provide recommendations on: 1) whether the product codes on the proposed 506J Device List meet the requirements for a critical device as outlined in section 506J of the FD&C Act, 2) whether the proposed 506J Device List includes the appropriate device types (by product code) that are critical to public health during a PHE, 3) if additional device types (by product code) should be considered for inclusion on the list, 4) how supply chain resilience and vulnerabilities should be considered when determining product codes for inclusion or exclusion from the list, and 5) how specific characteristics of a product code or device type (e.g., single-use disposable vs. multi-patient reusable devices; convenience kits; and capital equipment) should be considered when determining product codes for inclusion or exclusion from the list.

iii. Background and Authorities

a. Overview

The FDA Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health by assuring that patients and providers have

timely and continued access to safe, effective, and high-quality medical devices. The FDA's role in assuring availability of medical devices includes visibility into the supply chains of critical devices. Early notifications to the FDA from manufacturers about a permanent discontinuance or an interruption in the manufacture of certain devices are critical for preventing and mitigating medical device shortages that impact delivery of healthcare to patients.

The 506J Device List is intended to assist manufacturers in providing timely notifications to the FDA for those devices that are "critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery" (section 506J[a][1]). As experience has demonstrated, the earlier the FDA is notified about an impending supply chain disruption for critical devices, the more effective the FDA can be at working with stakeholders (e.g., manufacturers, distributors, providers, healthcare systems, group purchasing organizations, and suppliers) and federal partners to prevent significant harm to patients that can result from shortages.

The FDA uses information provided through 506J notifications to conduct supply chain assessments and inform the implementation of both regulatory mitigations (e.g., expediting 510(k) reviews and inspections, emergency use authorizations, enforcement discretion, letters to healthcare providers, conservation strategies) and non-regulatory mitigations (e.g., priority request letters, Defense Production Act [DPA] priority ratings, transportation prioritization). These mitigations, when applied early, can prevent shortages that impact patients, healthcare providers, and our most vulnerable populations (e.g., pediatrics, pregnant women, immunocompromised). In addition, information about the supply chains of critical devices is needed for predicting vulnerabilities and pre-positioning mitigations, building resiliency in these supply chains.

b. FDA 506J Medical Device Shortage Authorities

On March 27, 2020, the CARES Act was signed into law. This legislation gave the FDA, for the first time, authorities to help prevent or mitigate medical device shortages.

Specifically, section 3121 of the CARES Act amended the FD&C Act by adding section 506J to the statute. Section 506J of the FD&C Act requires manufacturers to notify the FDA of a permanent discontinuance or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device during, or in advance of, a PHE declared by the Secretary under section 319 of the Public Health Service Act.

On December 29, 2022, the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) was signed into law as part of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 (hereafter referred to as the "FY 2023 Omnibus"). Section 2514 of the FY 2023 Omnibus amended section 506J to add section 506J(h), "Additional Notifications" and directed the FDA to issue draft guidance to facilitate voluntary notifications. Additionally, section 2514 of the FY 2023 Omnibus directed the FDA to issue or revise guidance regarding requirements under section 506J and include a list of each device by product code for which a manufacturer of such device is required to notify the FDA in accordance with section 506J during, or in advance of, a PHE. Product codes, consisting of three letters, are assigned by the Agency according to regulations described in 21 CFR Part 860.[1] Product codes provide a method for classifying and tracking medical devices across the total product life cycle.

In accordance with the FY 2023 Omnibus, and to assist manufacturers in providing timely, informative notifications about changes in the production of certain medical device products that will help prevent or mitigate shortages of devices during, or in advance of, a PHE, in November 2023, the FDA issued the draft guidance, "Select Updates for the 506J Guidance: 506J Device List and Additional Notifications." The draft guidance includes a list of device product codes (the 506J Device List) for which a manufacturer of such devices is required to notify the FDA in accordance with section 506J of the FD&C Act and clarifies that manufacturers may submit voluntary

[1] Medical Device Classification Product Codes - Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff

notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a PHE.

For additional detail on the FDA's shortage reporting authorities and section 506J of the FD&C Act, please refer to FDA's 506J Device List website for the following 506J related documents: "Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act" final guidance and "Select Updates for the 506J Guidance: 506J Device List and Additional Notifications" draft guidance.

iv. The 506J Device List

a. Criteria and Methodology

In developing the proposed 506J Device List, the FDA considered factors consistent with the language in section 506J of the FD&C Act, including whether a device is critical to public health during specific PHEs or any PHE.

The FDA's consideration of whether a device is critical to a PHE includes, but is not limited to:

- Whether the device is used to diagnose, treat, monitor, or prevent a serious disease or medical condition; and if the device is "life-supporting, life-sustaining or intended for use in emergency medical care or during surgery" (section 506J[a][1]) or for which the FDA has determined "that information on potential meaningful supply disruptions" is needed pursuant to section 506J(a)(2);
- Whether the lack of availability of the device is reasonably likely to cause serious injury or death to patients, healthcare workers, or others if it is not available and there are no suitable alternatives.
    - The FDA considers a "suitable alternative" to be an alternate FDA-approved device, procedure, drug, or other intervention used to address a medical condition or disease. Whether or not a medical device has suitable alternatives is often an indicator of that device's criticality. If no alternate

> devices, procedures, drugs, or interventions can be used in the absence of a certain medical device to achieve an equivalent clinical outcome, then a lack of availability of that medical device may cause serious injury or death to patients, health care workers, or others.

The FDA also considered the resiliency of device types and characteristics of specific categories of devices (e.g., single-use disposable vs. multi-patient reusable devices) that make them more vulnerable or more resilient to sudden increases in demand and/or supply chain disruptions.

Resiliency factors considered include, but were not limited to, market share, number of manufacturers, manufacturer location (geolocation), and known raw material or component supply chain vulnerabilities or resiliency. Categories of device types that were examined included: 1) single-use disposable vs. multi-patient reusable devices, 2) convenience kits (two or more different medical devices packaged together for the convenience of the user [21 CFR 801.3]), and 3) capital equipment (e.g., magnetic resonance imaging [MRI] systems), which are often purchased months in advance of installation.

Knowledge gained from the FDA's experience with prior supply chain disruptions and the Coronavirus Disease 2019 (COVID-19) PHE was also taken into consideration during deliberations. In addition, factual inputs from work undertaken as part of the Critical Medical Device List (CMDL) process informed the development of the 506J Device List. The CMDL was developed in collaboration with healthcare providers, healthcare systems and other medical device stakeholders as a deliverable of the National Strategy for a Resilient Public Health Supply Chain ("National Strategy"). The National Strategy (published in 2021) outlines the vision, goals, and objectives for developing a resilient public health supply chain as outlined in the Executive Order on a Sustainable Public

Health Supply Chain (EO 14001).[2] Specifically, information from members of the CMDL Task Group of Experts and clinical subject matter experts that presented to the CMDL Task Group pf Experts on device criticality and resiliency were considered during the workgroup's deliberations. Clinical experts (healthcare providers) and subject matter experts from healthcare systems advised the CMDL Task Group of Experts on the criticality of a device and the availability of alternatives. Experts discussed delivery of clinical care in emergent medical situations and for vulnerable populations.

The proposed 506J Device List represents the culmination of the FDA's work: compiling an initial list; determining if each product code on the list met the statutory criteria; considering device resiliency characteristics and the availability of suitable alternatives, based in part of the FDA's past experience with supply chain disruptions and COVID-19; and consideration of factual inputs to the CMDL process.

b. Organization of the 506J Device List

Section 506J of the FD&C Act requires the FDA to develop the 506J Device List by product code. This method of identifying devices that are subject to 506J notification facilitates timely reporting and assists manufacturers in understanding their reporting requirements.

The FDA has classified and described over 1,700 distinct types of devices and organized them in the Code of Federal Regulations (CFR) into 16 medical specialty "panels" such as Cardiovascular devices or Ear, Nose, and Throat devices. [3] A list of these panels can be found in Parts 862-892 in the CFR. For the purposes of this meeting and to facilitate review by the committee members, the product codes proposed for inclusion on the 506J Device List are grouped according to their medical specialty panel, as seen in Table 1.

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[2] *See* Executive Order on a Sustainable Public Health Supply Chain, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-a-sustainable-public-health-supply-chain

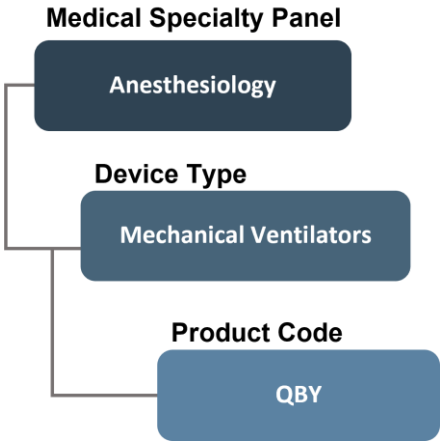
[3] *See* Device Classification Panels, https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels

Figure 1, below, illustrates the use of this organizational structure with an example product code (QBY [Positive Airway Pressure System]).

Table 1. Organization of Proposed 506J Device List for Panel Review

Medical Specialty Panel	Regulation Citation (21CFR)
Anesthesiology	Part 868
Cardiovascular	Part 870
Clinical Chemistry and Clinical Toxicology	Part 862
Ear, Nose, and Throat	Part 874
Gastroenterology-Urology	Part 876
General and Plastic Surgery	Part 878
General Hospital	Part 880
Hematology and Pathology	Part 864
Immunology and Microbiology	Part 866
Neurology	Part 882
Obstetrics and Gynecology	Part 884
Orthopedic	Part 888
Physical Medicine	Part 890
Radiology	Part 892

Figure 1. Example of 506J Device List Product Code Organized by Medical Specialty Panel



c. Specific Categories of Devices and FDA's Determination

Single-Use Disposable vs. Multi-patient Reusable Devices

Single-use disposable medical devices[4] that met the criteria in section 506J(a)(1) of the FD&C Act (e.g., N95 respirators, syringes, hypodermic needles, catheters, gowns, gloves, wound dressings) have been included on the proposed 506J Device List. The FDA considers these devices vulnerable to supply chain disruptions and/or acute increases in demand. As demonstrated during the COVID-19 PHE and in other shortage events such as those triggered by natural disasters, acute and prolonged increases in demand or disruptions in the availability of raw materials (e.g., medical grade resins during and long after Winter Storm Uri) have led to shortages of critical medical devices that have impacted patients and often, our most vulnerable populations (e.g., pediatric).

On the other hand, many multi-patient reusable medical devices (e.g., hospital beds, personal assist mobility devices, intravenous poles, and stethoscopes) are ubiquitous in healthcare settings. While needed for delivery of healthcare in emergency situations, the FDA generally considered these device types more resilient to sudden increases in demand and potential supply chain disruptions and therefore unlikely to experience a shortage. With the exception of wheeled stretchers (product code FPO, required for moving patients during an emergency [trauma or CBRN event]) and certain capital equipment described below, these device types were not proposed for inclusion on the proposed 506J Device List.

Convenience Kits

Convenience kits, two or more different medical devices packaged together for the convenience of the user,[5] were not included on the proposed 506J Device List. Instead, the FDA considered whether individual components commonly contained within convenience kits met the statutory criteria for inclusion on the 506J Device List.

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[4] Devices that are "intended for use on one patient during a single procedure and not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labeling-recommendations-single-use-devices-reprocessed-third-parties-and-hospitals

[5] *Convenience kit* as defined in 21 CFR 801.3.

Consequently, if the component parts of a "convenience kit" met the criteria for inclusion, they were included on the proposed list and manufacturers should notify FDA of a permanent discontinuance or an interruption in the manufacture of an individual component within the kit during or in advance of a PHE. However, one kit – product code FCN (Urinary Drainage Collection Kit, For Indwelling Catheter) – was included on the list because of the: (1) clinical need for sterility when placing an indwelling urinary catheter, and (2) kit containing parts and components of a closed-system. The FDA does acknowledge that convenience kits are often necessary and utilized for patient safety and clinical expediency.

Capital Equipment

Capital equipment deemed critical for supporting continuity of healthcare delivery in the United States (e.g., ethylene oxide gas sterilizers) and those devices necessary for diagnosing and treating patients in an emergent or emergency medical situation (e.g., trauma or CBRN event) were included on the proposed 506J Device List (e.g., plain X-ray systems, computed tomography [CT] scan, and ultrasound systems). The FDA considered these device types critical to the diagnosis and treatment of a patient and potentially vulnerable to component shortages. Recent examples of supply chain vulnerabilities impacting these types of devices include the semiconductor shortages that impacted both the servicing of existing units and installation of new systems, especially in our rural and underserved communities.

d. The 506J Device List

The proposed 506J Device List contains 284 product codes that can be organized into 14 medical specialty panels. The majority (69%) of the product codes on the proposed 506J Device List fall under the purview of the Anesthesiology, Cardiovascular, Clinical Chemistry and Clinical Toxicology, and General Hospital panels. For the Panel's consideration, Table 2 provides a breakdown of the number of product codes by medical specialty.

Table 2. Number of Product Codes on Proposed 506J Device List by Medical Specialty Panel

Medical Specialty Panel	Number of Product Codes
Anesthesiology	46
Cardiovascular	57
Clinical Chemistry and Clinical Toxicology	46
Ear, Nose, and Throat	3
Gastroenterology-Urology	29
General and Plastic Surgery	19
General Hospital	48
Hematology and Pathology	4
Immunology and Microbiology	4
Neurology	13
Obstetrics and Gynecology	3
Orthopedic	3
Physical Medicine	2
Radiology	7

Overview of the 506J Device List by Medical Specialty Panel

This section is intended to provide a high-level overview of device types and associated product codes included on the proposed 506J Device List by medical specialty panel. The proposed 506J Device List in its entirety can be found in the accompanying documents included in the panel pack.

1. **Anesthesiology**

   Product codes in the in the Anesthesiology medical specialty include those used to deliver anesthesia and those required for optimal oxygenation and ventilation. Device types include but are not limited to endotracheal tubes, laryngoscopes, nasal cannulas, mechanical ventilators (e.g., high frequency, positive airway pressure), anesthesia machines, and airway components and accessories (e.g., circuits, tubing, and masks).

2. **Cardiovascular**

   Product codes that are organized under the Cardiovascular medical specialty include those required for maintaining adequate perfusion of tissues and organs with oxygenated blood. Product codes include but are not limited to devices required to perform cardiopulmonary bypass procedures and angioplasty, as well as cardiovascular diagnostic and screening devices (e.g., electrocardiograph (ECG) and blood pressure system).

3. **Clinical Chemistry and Clinical Toxicology**

   Product codes proposed for inclusion on the 506J Device List in the Clinical Chemistry and Clinical Toxicology medical specialty include those used to support specimen collection and testing of patient specimens (e.g., vacuum collection bottle, sterile specimen container and newborn screening specimen collection paper). Specifically, devices required to analyze blood samples for certain biological markers and metabolic disturbances that may be present in critically ill patients (e.g., cardiac enzymes, complete metabolic panel tests) and devices used to monitor and maintain glucose levels (e.g., insulin pumps and glucose sensors) are included in this specialty.

4. **Ear, Nose, and Throat**

   Product codes proposed for inclusion on the 506J Device List in the Ear, Nose, and Throat medical specialty includes bronchoscopes, bronchoscope accessories, and tonsil suction tubes.

5. **Gastroenterology-Urology**

   Product codes proposed for inclusion on the 506J Device List in the Gastroenterology-Urology medical specialty include those required for delivering life-sustaining and life-supporting treatment of patients with acute or chronic renal failure and those that are used for gastrointestinal procedures, including endoscopic procedures and gastrointestinal stent placement. Product codes

representing device types that are required to perform hemodialysis, peritoneal dialysis, kidney perfusion, and continuous renal replacement therapy (e.g., dialysate delivery systems and accessories) are also included in this specialty.

6. **General and Plastic Surgery**

   Product codes in the General and Plastic Surgery medical specialty include those that are used in general surgeries (e.g., surgical drapes, ventricular catheters); bleeding control (e.g., hemostatic agents, cautery devices); incision and wound closure (e.g., sutures, clips); and wound care (e.g., gauze, tape, dressing).

7. **General Hospital**

   Product codes that are organized under the General Hospital medical specialty include devices needed to support nutrition, fluid delivery, and basic physiologic functions. Product codes include but are not limited to catheters, ports, syringes, needles, infusion pumps, intravenous (IV) containers and stopcocks, and suction catheters. Devices necessary to protect wearers from the spread of infection or illness (e.g., public use respirators [N95s], non-sterile gloves, masks, gowns); those used to maintain a sterile surgical field (e.g., surgical gloves, gowns), and products used to disinfect and sterilize medical devices (e.g., disinfectant, disinfector) are also included in this category.

8. **Hematology and Pathology**

   Product codes in the Hematology and Pathology medical specialty include those required to test for coagulation abnormalities and monitor heparin therapy for the treatment of venous thrombosis or pulmonary embolism.

9. **Immunology and Microbiology**

   Product codes organized under the Immunology and Microbiology medical specialty include devices used for supporting the growth of bacterial pathogens, performing antimicrobial susceptibility testing and transporting patient specimens for detection of viral pathogens.

10. Neurology

Product codes in the Neurology medical specialty include instruments used in neurosurgical procedures (e.g., head holder, clip applier, drills, burrs, trephines), devices used to treat neurological conditions (e.g., central nervous system shunts, thrombus retriever) and devices to measure intracranial pressure and cerebral oxygen levels (e.g., cerebral oximeter).

11. Obstetrics and Gynecology

Product codes in the Obstetrics and Gynecology medical specialty include devices that are used for fetal monitoring and intrauterine dilation.

12. Orthopedic

Product codes in the Orthopedic medical specialty include devices used to perform orthopedic surgeries (e.g., fusion and pedicles screw systems).

13. Physical Medicine

Product codes in the Physical Medicine medical specialty include those used to immobilize fractures, strains, or sprains of the neck or trunk of the body.

14. Radiology

Product codes in the Radiology medical specialty include devices necessary for diagnostic imaging (e.g., x-ray, ultrasound) in an emergent medical situation (e.g., car accident, trauma) or a chemical, biological, radiation, nuclear (CBRN) event.

Finalizing the 506J Device List

The FDA intends to consider the information and recommendations from the Panel when finalizing the 506J Device List. The FDA also intends to consider comments submitted to the docket on the draft guidance, "Select Updates for the 506J Guidance: 506J Device List and Additional Notifications," and the docket for this Advisory Committee meeting (i.e., meeting of the General Hospital and Personal Use Devices Panel of the Medical

Devices Advisory Committee). The number for the docket opened for comment on topics covered at this Advisory Committee meeting is FDA-2023-N-4807-0001.

The FDA expects that the list will evolve over time and intends to periodically reevaluate the list. Any revisions to the 506J Device List will follow FDA's good guidance practices.[6]

[6] *See* 21 CFR 10.115(g)(4).

v. FDA Questions to the Panel

1. Do the device types (by product code) on the proposed 506J Device List meet the requirements for a critical device as outlined in section 506J of the FD&C Act?
    a. Are there device types (by product code) on the proposed 506J Device List that are not critical to public health during a public health emergency and should be removed from the list?
    b. Are there device types (by product code) that are not on the proposed 506J Device List that are critical to public health during a public health emergency and should be added to the list?
    c. What additional devices would be needed for national emergency preparedness?

2. How should supply chain resilience and vulnerabilities be considered when determining device types (by product code) for inclusion or exclusion on the 506J Device List?

3. How should the following device types be addressed with regard to the proposed 506J Device List?
    a. Single-use disposable vs. multi-patient reusable devices
    b. Convenience kits
    c. Capital equipment (e.g., imaging devices)