U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!

We'll get started in a few minutes

Today's Topic:

In Vitro Diagnostic Product (IVD) Classification

July 16, 2024

In Vitro Diagnostic Product (IVD) Classification

Brittany Schuck, PhD
Deputy Office Director
Office of Health Technology 7: Office of In Vitro Diagnostic Devices
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration

Learning Objectives

- Describe FDA's risk-based medical device classification
- Explain how to determine the classification and regulatory requirements for IVDs
  - Discuss how to search FDA's medical device databases
  - Provide examples
- Identify additional resources

Background

FDA uses a **risk-based** classification system to classify medical devices, **including IVDs**, according to the level of regulatory control that is necessary to reasonably assure product safety and effectiveness

Regulatory classification depends on the intended use of the device and the risk posed by the device

RISK

IVD Intended Use Considerations

Purpose of the IVD

- Aid in diagnosis
- Predict risk
- Monitor
- Identify population for whom a drug is effective, etc.

Disease or condition the device is intended to diagnose, monitor, predict risk of, etc.

- Renal disease
- Cardiovascular disease
- Therapeutic response, etc.

Test method

- Technology (PCR, mass spectrometry, immunoassay, etc.)
- Specimen type (serum, plasma, venous whole blood, capillary whole blood, dried blood spot, urine, saliva, etc.)
- Results reported (quantitative, qualitative, etc.)

Patient population

- Symptomatic or asymptomatic
- High-risk patient populations (e.g., ICU patients), etc.

Context of use

- In a laboratory
- Point of care (emergency rooms, doctor's offices)
- At home
- To be used in conjunction with other clinical information, etc.

Risk Considerations

Low Risk

Devices that present minimal potential for harm

Class I

Moderate Risk

Higher risk than Class I devices but not high risk

Class II

High Risk

Support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury

Class III

Medical Device Classification

FDA classifies devices by **generic type**:

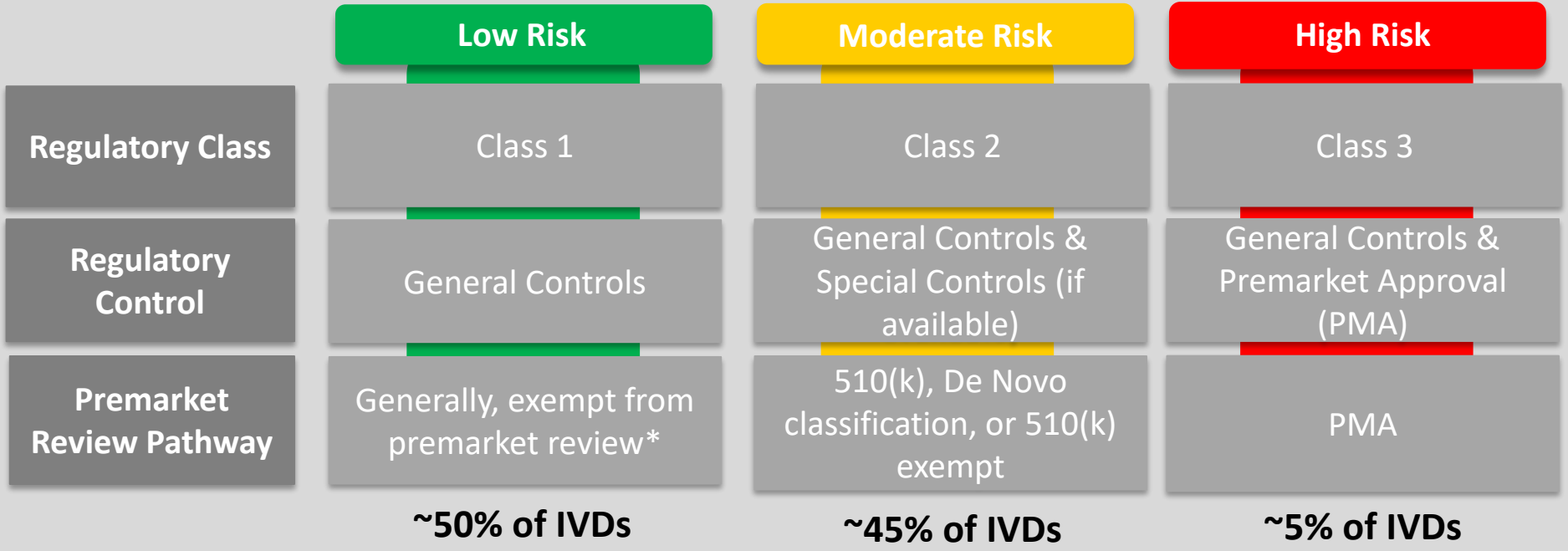
A "grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which **similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness**"

Each **specific device** falls under the classification for the generic device type

Generic Device Type: Next generation sequencing (NGS) based tumor profiling test

- Laboratory Manufacturer A's specific NGS tumor profiling test
- Laboratory Manufacturer B's specific NGS tumor profiling test
- Laboratory Manufacturer C's specific NGS tumor profiling test
- Non laboratory manufacturer X's NGS tumor profiling test
- Non laboratory manufacturer Y's NGS tumor profiling test

IVD Classification & Regulation



*Class I reserved devices and devices that meet the limitations to exemption (for example, see 21 CFR 862.9) require premarket review through a 510(k)

Classify Your Medical Device | FDA
IVD Regulation

Regulatory Controls

General Controls

Apply to **all medical devices, including IVDs,** unless exempted by regulation (as stated in the classification regulation).

Example General Controls

Control	Regulation (21 CFR Part)	Brief Description
Labeling Requirements	801, 809	Helps ensure appropriate information in provided to users
Medical Device Reporting Requirements	803	Report device-related serious injuries, deaths, and malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur
Establishment Registration Requirements	807	Register company with FDA
Device Listing Requirements	807	Identify devices with FDA
Quality System Requirements	820	Helps ensure devices consistently meet applicable requirements and specifications to assure that they are safe and effective

Regulatory Controls | FDA

Regulatory Controls

Special Controls

Special controls are specific regulatory requirements for **class II devices** and are generally **device type specific.**

Special controls assigned to a specific product can be found under the **device type specific regulation.**

Example Special Controls

Control
Performance standards
Postmarket surveillance
Special labeling requirements
Premarket data requirements
Guidelines

Regulatory Controls | FDA

Premarket Review Pathways

There are two premarket review pathways for devices that are of a type that has **already been classified or approved through a PMA by FDA**

Premarket Notification 510(k)

Generally moderate risk, Class II devices

Demonstrate device is as safe and effective as (i.e., substantially equivalent to) a legally marketed (predicate) device

- **For IVDs,** FDA reviews information supporting analytical validity, clinical validity, and safety prior to marketing.

Additional Resources:
Premarket Notification 510(k) (fda.gov)
CDRH Learn: The 510(k) Program (yorkcast.com)

Premarket Approval (PMA)

High risk, Class III devices

Demonstrate reasonable assurance of safety and effectiveness

- **For IVDs,** FDA reviews information supporting analytical validity, clinical validity, and safety **as well as manufacturing information** prior to marketing.

Additional Resources:
Premarket Approval (fda.gov)
CDRH Learn: Introduction to the Premarket Approval Application (PMA) Program (yorkcast.com)

De Novo Classification Requests

Marketing pathway to classify certain **novel** devices (i.e., those with new intended uses not yet classified or reviewed through a PMA) for which general controls alone (Class I), or general and special controls (Class II), can provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device

For IVDs, FDA reviews information supporting analytical validity, clinical validity, and safety prior to marketing and determines the level of regulatory control needed

If granted, establishes new "device type" along with classification regulation and necessary controls. The new device type is then regulated through 510(k), or may be exempt. For those regulated through 510(k), the De Novo device can serve as a predicate device. De Novo classification may establish the device type as Class I.

Additional Resources:

De Novo Classification Request (fda.gov)

CDRH Learn: The De Novo Program (yorkcast.com)

How to determine classification and regulatory requirements

Is the IVD of a type already classified or approved through a PMA?

Search the **product classification database**

If the IVD is of a type that is classified, the database includes the Class (I, II, or III), the type of submission (if any), and the classification regulation number (if applicable)

Class I and Class II devices

- In most cases, the database will include a link to the classification regulation. Use this link to identify the full description of the device type, applicable controls, and exemptions
- If there is no link to the classification regulation, search the De Novo database, using the product code, to identify the full description of the device type, applicable controls and exemptions

Class III devices

- The database will indicate that a PMA submission is required
- Most Class III devices do not have a classification regulation

What if the IVD is not of a type already classified or approved through a PMA?

Assess the **risk** of the IVD

If the manufacturer believes it is high risk, it likely requires a PMA. If the manufacturer believes it is low or moderate risk, it may be eligible for a de novo classification

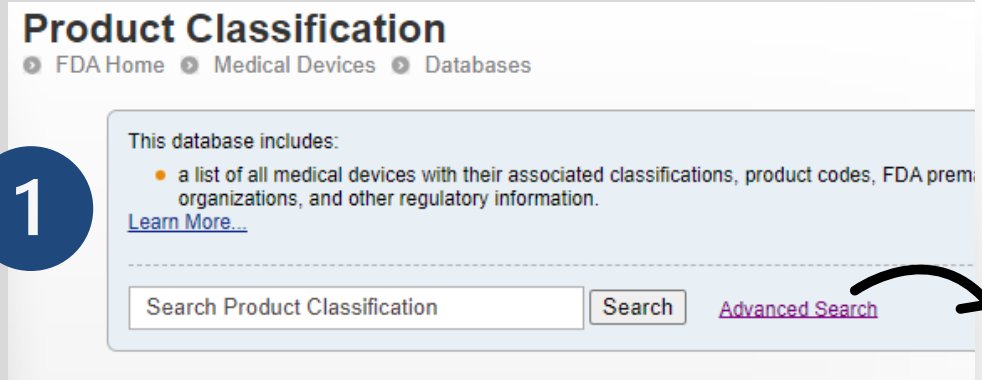
Proceed with submitting your premarket submission based on the assessed risk

If assistance is needed, seek feedback from FDA via Pre-Submission or 513(g)

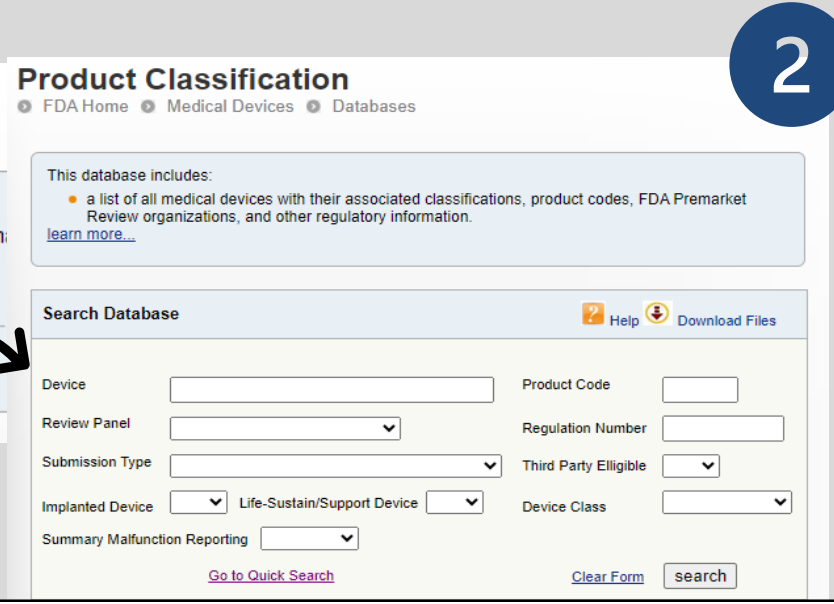
Medical Device Databases | FDA

Searching the Product Classification Database

Searches all medical devices and provides their associated classifications, product codes, FDA Premarket review office and division, and other regulatory information.



1. Search by key word – exact spelling



2. Selecting “Advanced Search” will provide more fields, if you want to use additional fields

Classification Regulations

Classification regulations for Class I and Class II medical device types are codified in Title 21 of the Code of Federal Regulations.

The classification regulations for existing IVDs are codified in 21 CFR Part 862, 21 CFR Part 864, and 21 CFR Part 866.

Class I

[Code of Federal Regulations]
[Title 21, Volume 8]
[CITE: 21CFR862.1095]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 862 -- CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

Subpart B - Clinical Chemistry Test Systems

Sec. 862.1095 Ascorbic acid test system.

(a) *Identification.* An **ascorbic acid** test system is a device intended to measure the level of **ascorbic acid** (vitamin C) in plasma, serum, and urine. **ascorbic acid** measurements are used in the diagnosis and treatment of **ascorbic acid** dietary deficiencies.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

Class II

New Search | Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[CITE: 21CFR862.3590]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 862 -- CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

Subpart D - Clinical Toxicology Test Systems

Sec. 862.3590 Meprobamate test system.

(a) *Identification.* A meprobamate test system is a device intended to measure meprobamate in human specimens. Measurements obtained by this device are used to detect the presence of meprobamate to diagnose the use or overdose of meprobamate or structurally-related drug compounds (e.g., prodrugs).

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include:

Class I Device Example

Example: Lactic Acid

Product Classification

FDA Home ▸ Medical Devices ▸ Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA prem
  organizations, and other regulatory information.

Learn More...

lactic acid | Search | Advanced Search

1 to 2 of 2 Results
for *lactic acid*

Results per page 10

New Search | Export To Excel | Help

Product Code	Device		Regulation Number	Device Class
KHP	Acid, Lactic, Enzymatic Method	Lactic Acid Test System	862.1450	1
NGD	Test, Lactic Acid, Over The Counter	Lactic Acid Test System	862.1450	1

Product Classification

FDA Home ▸ Medical Devices ▸ Databases

New Search | Back to Search Results

Device	Acid, Lactic, Enzymatic Method
Regulation Description	Lactic acid test system.
Regulation Medical Specialty	Clinical Chemistry
Review Panel	Clinical Chemistry
Product Code	KHP
Premarket Review	Division of Chemistry and Toxicology Devices (DCTD)
	Division of Chemistry and Toxicology Devices (DCTD)
Submission Type	510(K) Exempt
Regulation Number	862.1450
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Class I Device Example

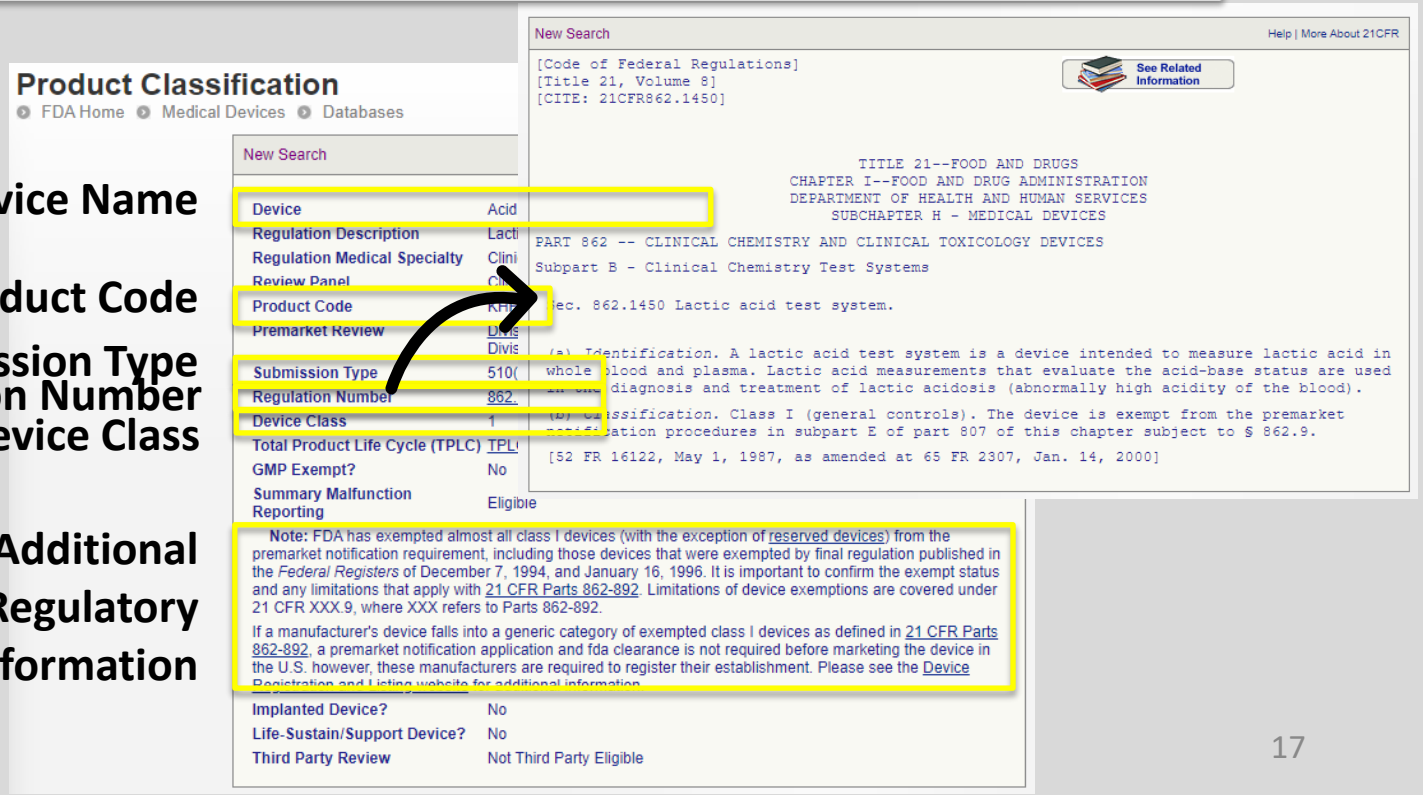
Example: Lactic Acid

Device Name

Product Code

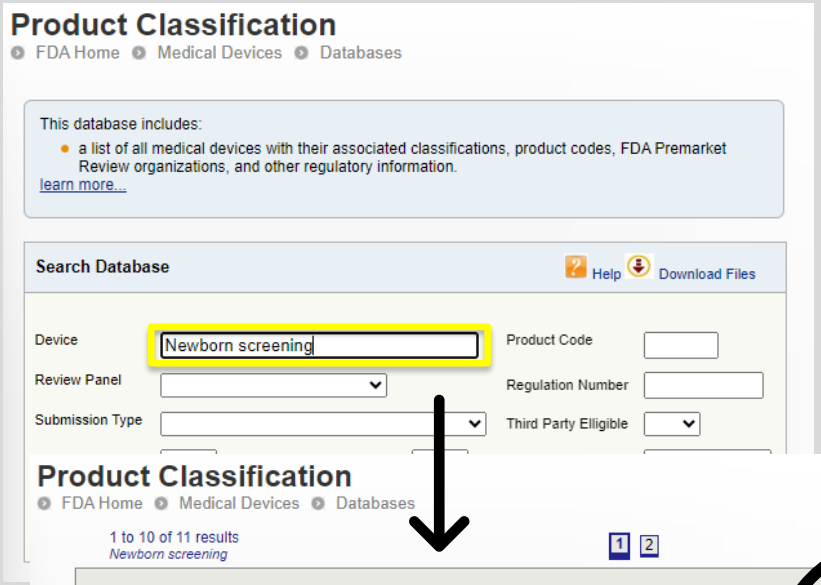
Submission Type
Regulation Number
Device Class

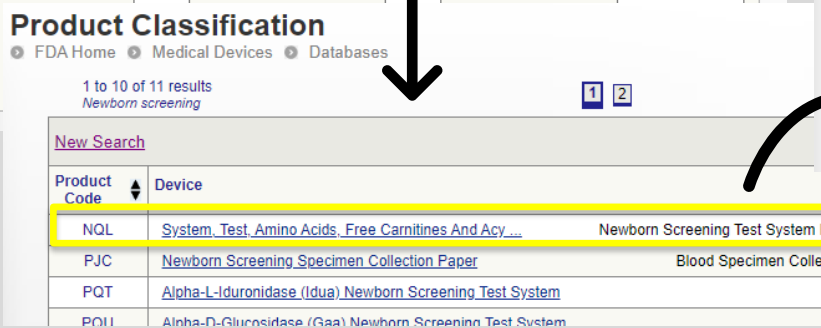
Additional Regulatory information

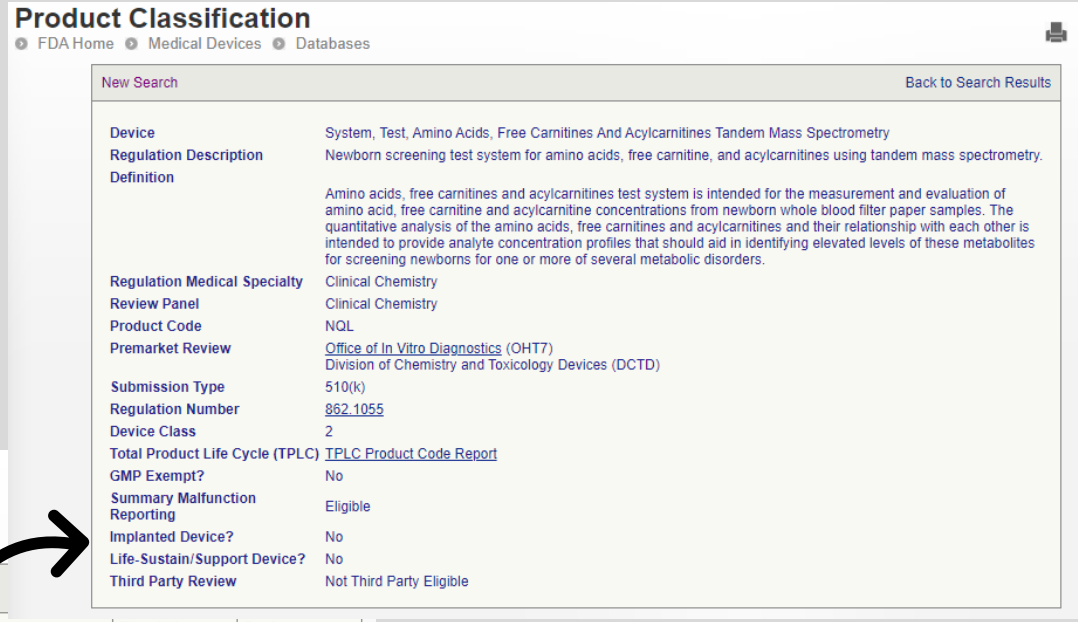


Class II Device Example

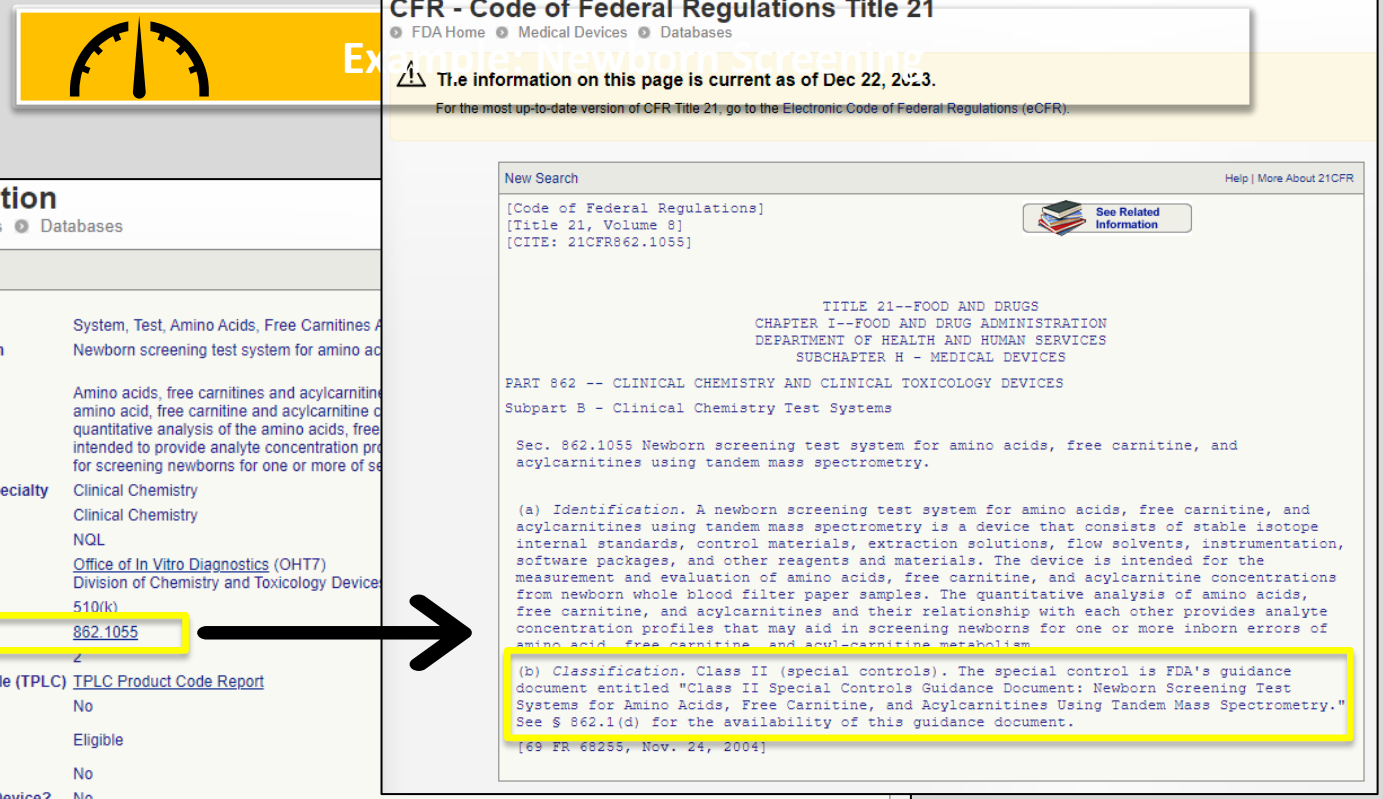
Example: Newborn Screening







Class II Device Example



Class II Device Example

Example: Newborn Screening

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry." See § 862.1(d) for the availability of this guidance document.

[69 FR 68255, Nov. 24, 2004]

Special Controls Documents named in the regulation can be found by searching Class II special controls documents on FDA's website. Manufacturers of this device type must address the specific risks to health identified in the document described.

Class II Device Example

Example: Newborn Screening

Product Classification Database

			862.1488	2
QCM	ß-Galactocerebrosidase (Galc) Newborn Screening Test System		862.1488	2
QJE	Muscular Dystrophy Newborn Screening Test		862.1506	2
PJI	Severe Combined Immunodeficiency Disorder (Scid) N ...	Newborn Screening Test For Severe Combin...	866.5930	2

Device	Severe Combined Immunodeficiency Disorder (Scid) Newborn Screening Test System
Regulation Description	Newborn screening test for severe combined immunodeficiency disorder (SCID).
Definition	A newborn screening test for severe combined immunodeficiency (SCID) intended for the detection of T-cell receptor excision circle (TREC) genomic DNA isolated from newborn blood specimens dried on filter paper. It is intended as an aid in screening newborns for severe combined immunodeficiency (SCID).
Physical State	The test consists of primers and probes to amplify and detect genomic DNA obtained from newborn peripheral blood dried on filter paper. The device includes reagents, instruments, software and consumables, and may integrate punching of a dried blood spot specimen from filter paper and may include controls and calibrators. The instrumentation enables quantitative result output based comparison between amplified specific targeted sequence relative to a standard or normalizer (e.g., alternate gene sequence). The instrumentation may also include mechanisms to store raw data.
Technical Method	The test system uses primers to amplify genomic DNA obtained from newborn peripheral blood dried on filter paper and probes to detect specific DNA targets of interest.
Target Area	Human peripheral blood
Regulation Medical Specialty	Immunology
Review Panel	Immunology
Product Code	PJI
Premarket Review	Division of Immunology and Hematology Devices (DIHD) Division of Immunology and Hematology Devices (DIHD)
Submission Type	510(k)
Regulation Number	866.5930
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Premarket notification submissions must include the following information:

(i) The intended use must indicate:

(A) The test is not intended for diagnostic use, or for screening of SCID-like syndromes, such as DiGeorge syndrome or Omenn syndrome; and

(B) The test is not intended to screen for less acute SCID syndromes, such as leaky SCID or variant SCID.

(ii) A detailed description of all components in the test that includes:

(A) A detailed description of the test components, all required reagents, instrumentation and equipment, including illustrations or photographs of nonstandard equipment or methods;

(B) Detailed documentation of the device software including, but not limited to, standalone software applications and hardware-based devices that incorporate software;

(C) Specifications for the filter paper, which must be appropriately labeled for in vitro diagnostic use, to be used in specimen collection and how it will be used in specimen collection validation. These specifications must include: descriptive characteristics of the filter paper, instructions on how a lab should choose the appropriate filter paper, chemical properties of the filter paper, interference concerns associated with the chemicals in the filter paper, absorption properties of the filter paper, punch size, absorption capacity, testing for homogeneity of punches, diameter of the circle for the dried blood spot aliquot, absorption time, physical composition, and number and size of punches to be tested;

(D) Methodology and protocols for detection of T-cell receptor excision circles and methods for determination of results. The cutoff must be selected before conducting clinical and analytical studies;

(E) A description of the result outputs along with sample reports. Sample reports must include the scale used in reporting of results (*e.g.*, TREC copies/[micro]L) and the range of values that will be reported out; and

(F) A description of appropriate internal and external controls that are recommended or provided. The description must identify those control elements that are incorporated into the testing procedure.

(iii) Information that demonstrates the performance characteristics of the test, including:

For SCID newborn screening test systems, the special controls are included within the classification regulation

Class II Device Example

Example: Newborn Screening

Product Classification Database

			862.1488	2
QGM	ß-Galactocerebrosidase (Galc) Newborn Screening Test System		862.1488	2
QJE	Muscular Dystrophy Newborn Screening Test		862.1506	2
PJI	Severe Combined Immunodeficiency Disorder (Scid) N...	Newborn Screening Test For Severe Combin...	866.5930	2

New Search | Back to Search Results

Device	Spinal Muscular Atrophy Newborn Screening Test System
Definition	A Spinal Muscular Atrophy (SMA) newborn screening test system is a prescription device intended to detect homozygous deletion of exon 7 or other similar mutations in the SMN1 (Survival Motor Neuron 1) gene of DNA obtained from dried blood spot specimens on filter paper using a polymerase chain reaction-based test as an aid in screening newborns for SMA. Presumptive positive results are intended to be followed up by diagnostic confirmatory testing.
Physical State	May include a multiplex multigene qualitative gene region specific amplification detection test system. The device may include a use for newborn screening. Should not include devices using sequencing-based detection methods.
Technical Method	Uses a multiplex polymerase chain reaction (PCR) to amplify DNA variants located on specific targeted genes using non-sequencing-based methods or with specific nucleic acid sequencing-based detection methods. When using sequencing-based detection methods, variants are identified by comparison to a specified reference sequence.
Target Area	Human clinical specimens
Regulation Medical Specialty	Immunology
Review Panel	Molecular Genetics
Product Code	QUE
Premarket Review	Division of Molecular Genetics and Pathology (DMGP) Division of Molecular Genetics and Pathology (DMGP)
Regulation Number	866.5980
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

De Novo Database

Search Database — Help | Download Files

Denovo Number | Product Code: QUE
510(k) Number | Priority Review
Panel | Device Name
Center | Requester Name
Decision Date | to
Sort By: Decision Date (descending)
Clear Form | search

New Search | Download Files | More About De Novo

Device Name	Requester	De Novo Number	510(k) Number	Decision Date
Eonis SCID-SMA Kit	PerkinElmer Inc.	DEN200044		11/09/2022

Device Classification Name	Spinal Muscular Atrophy Newborn Screening Test System
De Novo Number	DEN200044
Device Name	Eonis SCID-SMA Kit
Requester	PerkinElmer Inc. 940 Winter Street Waltham, MA 02451
Contact	Casey Fox
Regulation Number	866.5980
Classification Product Code	QUE
Date Received	07/08/2020
Decision Date	11/09/2022
Decision	Granted (DENG)
Classification Advisory Committee	Immunology
Reclassification Order	Reclassification Order
FDA Review	Decision Summary
Type	Direct

Class II Device Example

Example: Newborn Screening

De Novo Database

Device Classification Name	Spinal Muscular Atrophy Newborn Screening Test System
De Novo Number	DEN200044
Device Name	Eonis SCID-SMA Kit
Requester	PerkinElmer Inc. 940 Winter Street Waltham, MA 02451
Contact	Casey Fox
Regulation Number	866.5980
Classification Product Code	QUE
Date Received	07/08/2020
Decision Date	11/09/2022
Decision	Granted (DENG)
Classification Advisory Committee	Immunology
Review Advisory Committee	
Reclassification Order	Reclassification Order
FDA Review	
Type	Direct

Reclassification Order: DEN200044

FDA U.S. FOOD & DRUG ADMINISTRATION

PerkinElmer Inc.
Casey Fox, Ph.D.
Sr. Manager Regulatory Affairs
940 Winter Street
Waltham, MA 02451

Re: DEN200044
Trade/Device Name: Eonis™ SCID-SM
Regulation Number: 21 CFR 866.5980
Regulation Name: Spinal Muscular Atro
Regulatory Class: Class II
Product Code: QUE
Dated: July 7, 2020
Received: July 8, 2020

Dear Dr. Fox:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has comple
prescri

FDA identifies this generic type of device as:

Spinal Muscular Atrophy newborn screening test system. A Spinal Muscular Atrophy (SMA) newborn screening test system is a prescription device intended to detect homozygous deletion of

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

DEN200044 - Casey Fox, Ph.D. Page 2

exon 7 or other similar mutations in the SMN1 (Survival Motor Neuron 1) gene of DNA obtained from dried blood spot specimens on filter paper using a polymerase chain reaction-based test as an aid in screening newborns for SMA. Presumptive positive results are intended to be followed up by diagnostic confirmatory testing.

In combination with the general controls of the FD&C Act, the Spinal Muscular Atrophy newborn screening test system is subject to the following special controls:

blood specimens dried on a filter paper and for use on the QuantStudio™ Dx Real-Time PCR instrument.

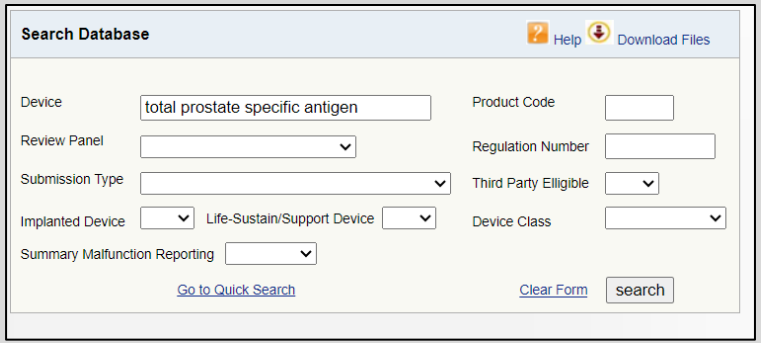
This test is only intended for use for screening of SMA that bear the homozygous deletion of SMN1 exon 7.

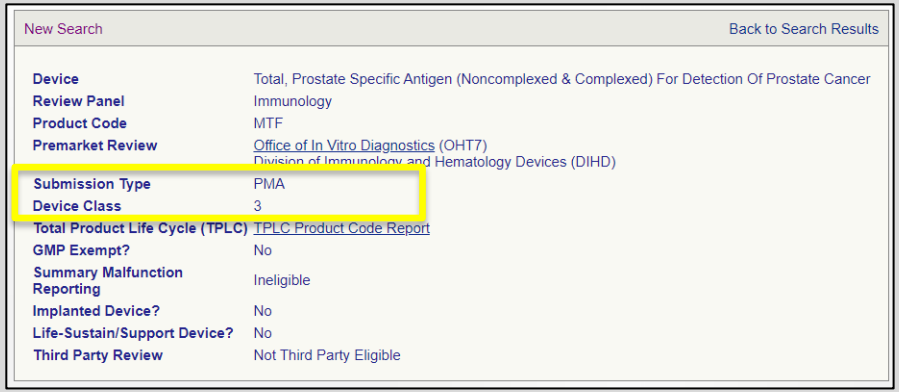
This test is not intended for use as a diagnostic test and a positive screening result should be followed by confirmatory testing.

Class III Device Example

Example: Total Prostate Specific Antigen to Aid in Detection of Prostate Cancer

Product Classification Database





Class III Device Example

Example: Total Prostate Specific Antigen to Aid in Detection of Prostate Cancer

Product Classification Database

Product Classification

FDA Home › Medical Devices › Databases

1 to 5 of 5 Results
for *prostate specific antigen*

Results per page 10

New Search | Export To Excel | Help

Product Code	Device		Regulation Number	Device Class
LTJ	Prostate-Specific Antigen (Psa) For Mana ...	Tumor-Associated Antigen Immunological T...	866.6010	2
MTF	Total, Prostate Specific Antigen (Noncomplexed & Complexed) For Detection Of Prostate Cancer			3
MTG	Test, Prostate Specific Antigen, Free, (Noncomplexed) To Distinguish Prostate Cancer From Benign Con...			3
NAF	Antigen(Complexed),Prostate Specific,(Cpsa)			3
OWM	Prostate-Specific Antigen (Psa) For Prog ...	Gene Expression Profiling Test System Fo...	866.6040	2

Class III Device Example

Example: Total Prostate Specific Antigen to Aid in Detection of Prostate Cancer

Product Classification Database

Product Classification

FDA Home › Medical Devices › Databases

1 to 5 of 5 Results
for *prostate specific antigen*

Results per page 10

New Search | Export To Excel | Help

Product Code	Device		Regulation Number	Device Class
LTJ	Prostate-Specific Antigen (Psa) For Mana ...	Tumor-Associated Antigen Immunological T...	866.6010	2
MTF	Total, Prostate Specific Antigen (Noncomplexed & Complexed) For Detection Of Prostate Cancer			3
MTG	Test, Prostate Specific Antigen, Free, (Noncomplexed) To Distinguish Prostate Cancer From Benign Con...			3
NAF	Antigen(Complexed),Prostate Specific,(Cpsa)			3
OWM	Prostate-Specific Antigen (Psa) For Prog ...	Gene Expression Profiling Test System Fo...	866.6040	2

Class III Device Example

Example: Total Prostate Specific Antigen to Aid in Detection of Prostate Cancer

Product Classification Database

New Search | Back to Search Results

Device	Prostate-Specific Antigen (Psa) For Management Of Prostate Cancers
Regulation Description	Tumor-associated antigen immunological test system.
Regulation Medical Specialty	Immunology
Review Panel	Immunology
Product Code	LTJ
Premarket Review	Office of In Vitro Diagnostics (OHT7) Division of Immunology and Hematology Devices (DIHD)
Submission Type	510(k)
Regulation Number	866.6010
Device Class	2

21 CFR

PART 866 -- IMMUNOLOGY AND MICROBIOLOGY DEVICES

Subpart G - Tumor Associated Antigen immunological Test Systems

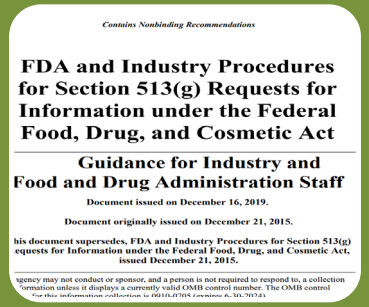
Sec. 866.6010 Tumor-associated antigen immunological test system.

(a) *Identification.* A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) *Classification.* Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled "Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s) to FDA," and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.

[62 FR 66005, Dec. 17, 1997]

Classification and Regulatory Pathway Questions?



Contains Nonbinding Recommendations

FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 16, 2019.

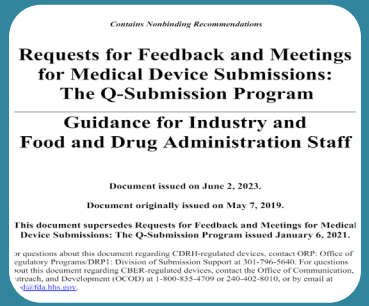
Document originally issued on December 21, 2015.

his document supersedes, FDA and Industry Procedures for Section 513(g) equests for Information under the Federal Food, Drug, and Cosmetic Act, issued December 21, 2015.

gency may not conduct or sponsor, and a person is not required to respond to, a collection formation unless it displays a currently valid OMB control number. The OMB control

513(g): Device Classification Information Request

- Formal request to the FDA for classification information and regulatory requirements for a particular product
- Guidance: FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act



Contains Nonbinding Recommendations

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 2, 2023.

Document originally issued on May 7, 2019.

This document supersedes Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program issued January 6, 2021.

r questions about this document regarding CDRH-regulated devices, contact ORP: Office of egulatory Programs/DRP1: Division of Submission Support at 301-796-5640. For questions bout this document regarding CBER-regulated devices, contact the Office of Communication, utreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at

Pre-Submission Request

- Request for FDA feedback on specific questions about a specific product → can include requests for feedback on regulatory pathway
- Guidance: Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

Summary

- FDA classifies medical devices based on risk
- The risk and intended use of a device determines the extent of regulatory controls
- FDA's medical device databases are available to help device manufacturers determine the appropriate regulatory controls for IVDs
- Device Determination and Pre-Submission requests are available to assist with classification and regulatory pathway questions

Next Webinar

Laboratory Developed Tests | FDA

Date
August 22, 2024

Time
1:00 – 2:30 PM ET

Topic
In Vitro Diagnostic Products (IVDs) - MDR Requirements, Correction and Removal Reporting Requirements, and Quality System Complaint Requirements

Please submit questions in advance to:
CDRHWebinars@fda.hhs.gov

Resources and References

Slide Number	Resource	URL
	In Vitro Diagnostic Product Website	www.fda.gov/medical-devices/in-vitro-diagnostics
	Direct link to Laboratory Developed Test Website (on the IVD website)	www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests
	510(k) Premarket Notification Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
	Premarket Approval (PMA) Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
	Device Classification Under Section 513(f)(2)(De Novo) Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm
8	Classify your Medical Device	www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
8	Reserved Medical Devices	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/3151.cfm
8	IVD Regulation	www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation
9	21 CFR 801 - Labeling	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=801

Resources and References

Slide Number	Resource	URL
9	21 CFR 809 – In Vitro Diagnostic Products for Human Use	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=809
9	21 CFR 803 - Medical Device Reporting	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803
9	21 CFR 807 - Establishment Registration	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807
9	21 CFR 807 - Device Listing	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807
9	21 CFR 820 - Quality System/Good Manufacturing Practices	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820
9, 10	Regulatory Controls	www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls
11	Premarket Notification 510(k)	www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k
11	CDRH Learn: The 510(k) Program (yorkcast.com)	https://fda.yorkcast.com/mediasite/Play/d91af554691c4260b5eca0b2a28e636b1d
11	Premarket Approval	www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma

Resources and References

Slide Number	Resource	URL
11	CDRH Learn: Introduction to the Premarket Approval Application (PMA) Program (yorkcast.com)	https://fda.yorkcast.com/mediasite/Play/97aec4c92a9b433c8342618d19fa9c9e1d
12	De Novo	www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request
12	CDRH Learn: The De Novo Program (yorkcast.com)	https://fda.yorkcast.com/mediasite/Play/9058dda0731f4cbdaf8ee37be10a9eb51d
13, 16	Product Classification Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
16	Medical Device Database	www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
14	CFR – Code of Federal Regulations Title 21	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
14	21 CFR 862	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=862
14	21 CFR 864	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=864
14	21 CFR 866	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=866

Resources and References

Slide Number	Resource	URL
20	Class II Special Controls Documents	www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents
28	FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act	www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic
28	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

Resources and References

Slide Number	Resource	URL
32	FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act	www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic
32	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program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Previously Submitted Questions

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  - CDRH Learn
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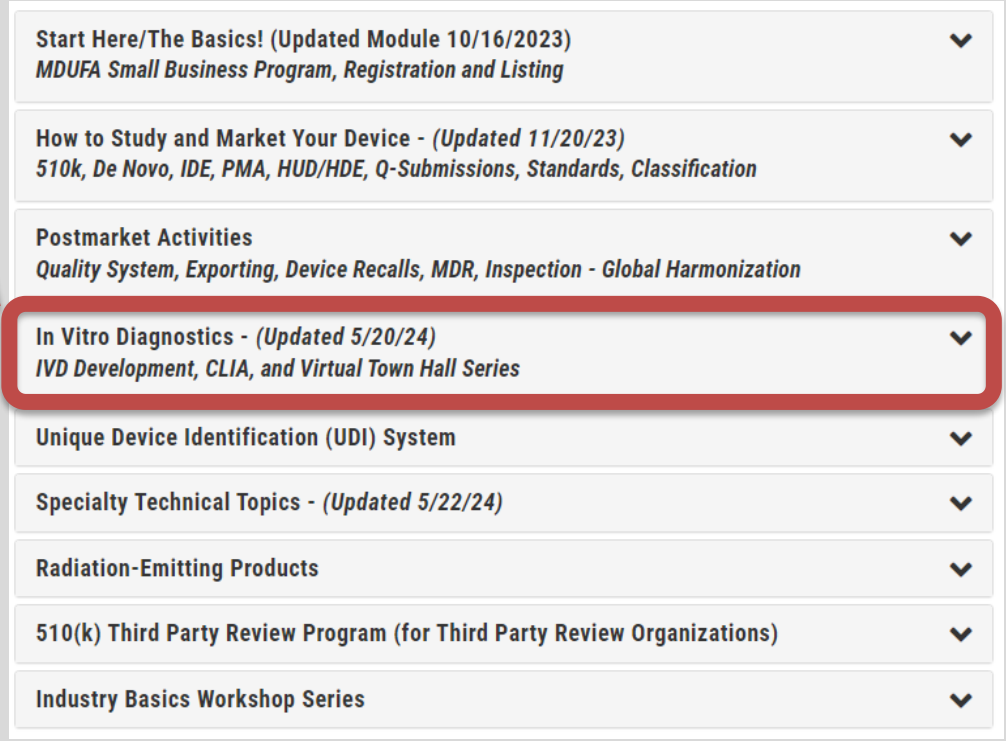
- **Upcoming Webinars**
  - www.fda.gov/CDRHevents

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