Meeting Agenda

MORNING	
9:00 a.m.	
9:20 a.m.	
9:30 a.m.	
10:15 a.m.	
10:30 a.m.	
11:15 a.m.	
11:30 a.m.	

AFTERNOON	
12:30 p.m.	– *Lunch* –
1:10 p.m.	Working Session 1 - FDA Questions
2:30 p.m.	– *Break* –
2:45 p.m.	Working Session 2 - FDA Questions
3:30 p.m.	Panel Deliberations
4:30 p.m.	FDA and Stakeholder Summations
5:00 p.m.	Adjourn

General Hospital and Personal Use Devices Panel of the Medical Device Advisory Committee

February 6, 2024

Discussion on Medical Device Supply Chain Resiliency, Shortages & Proposed 506J Device List

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Director, Office of Supply Chain Resilience (OSCR)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health (CDRH)

Presentation Overview

- **Meeting Objectives**
- **Legislative Overview**
- **How FDA uses 506J notifications**
- **Criteria and development of the proposed 506J Device List**
- **Overview of the 506J Device List**

Meeting Objectives

- **Obtain feedback on the proposed 506J Device List**
  - Whether the proposed devices meet the requirements outlined in section 506J of the FD&C Act
  - How supply chain resilience and vulnerabilities should be considered when determining device types (by product code) for inclusion or exclusion on the 506J Device List?
  - How specific characteristics of a device type should be considered
    - Single-use disposable vs. multi-patient reusable devices
    - Convenience kits
    - Capital equipment (e.g., imaging devices)
  - Additional considerations with respect to pandemic preparedness and response (per section 3302 of the Consolidated Appropriations Act, 2023 ("FY23 Omnibus"))

FDA CDRH Office of Strategic Partnerships and Technology Innovation (OST)

Office of Supply Chain Resilience (OSCR)

Strengthen public health supply chains by proactively monitoring, assessing, and communicating risks and vulnerabilities *and* working with stakeholders to prevent shortages before they occur

Protecting patients and providers means understanding the end-to-end supply chain for medical devices

Raw Materials ♦ Suppliers ♦ Manufacturers ♦ GPOs ♦ Distributors ♦ Transportation + Logistics ♦ Patients + Providers

Legislative Overview

The CARES Act and Section 506J: Manufacturer Obligations

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law on March 27, 2020

Coronavirus Aid, Relief, and Economic Security (CARES) Act

Section 506J of the Food, Drug, and Cosmetic Act

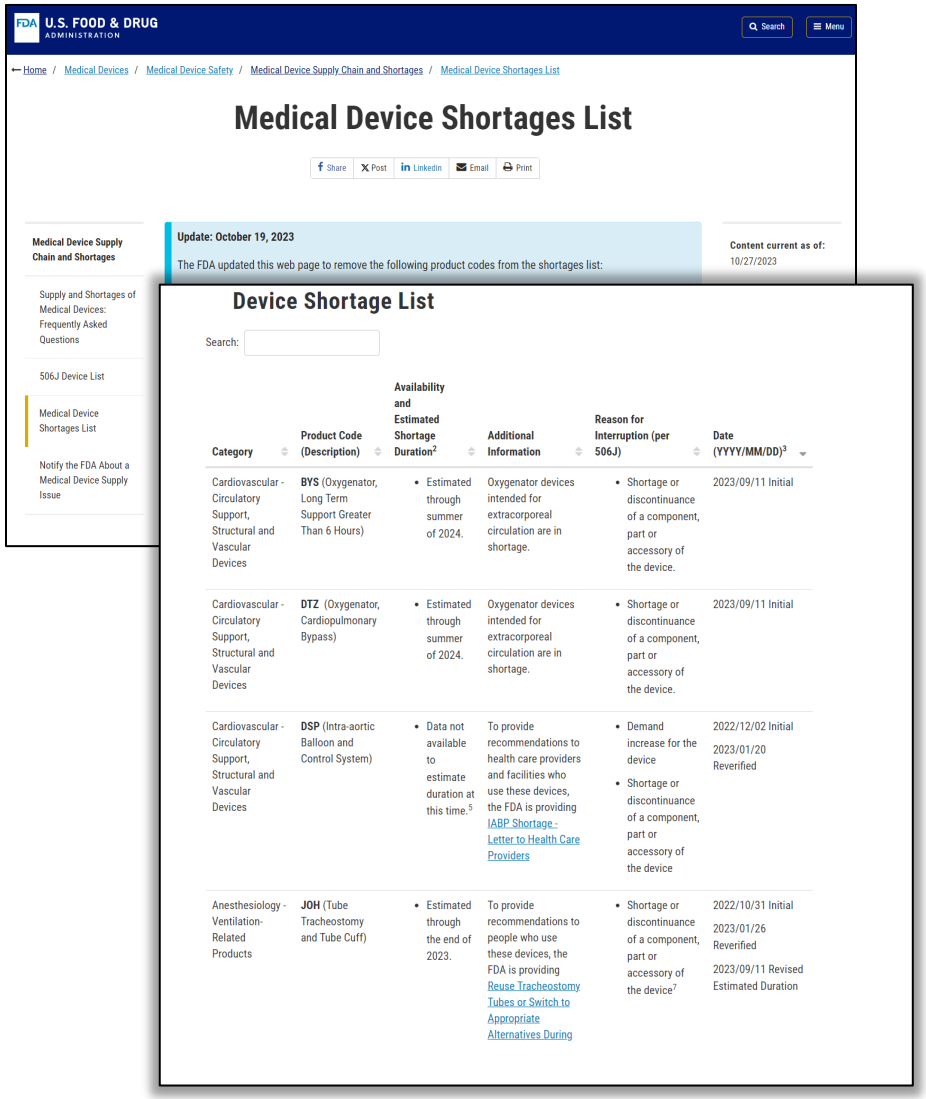
Gave FDA, for the first time, authorities to help prevent or mitigate medical device shortages

- **Requires manufacturers to notify FDA <u>during, or in advance of, a Public Health Emergency (PHE)</u> about:**
  - a permanent discontinuance 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/interruption

- **Devices for which such notifications are required include those:**
  - that are critical to public health during a PHE, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery (section 506J(a)(1)); or
  - for which FDA determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a PHE (section 506J(a)(2))

The CARES Act and Section 506J: FDA Obligations

The CARES Act gave the FDA, for the first time, authorities to help prevent or mitigate medical device shortages



- **Under this authority, FDA is also obligated to:**
  - establish and maintain a publicly available up-to-date list of devices that FDA determines to be in shortage (section 506J(g))
  - distribute information, "to the maximum extent practicable," on device discontinuance/interruption to appropriate organizations, including physician, health provider, patient organizations, and supply chain partners (section 506J(c))
  - issue letters to those who fail to timely report discontinuance/ interruption to FDA and post these "failure to notify" letters on the FDA website *unless* we determine it was issued in error (section 506J(e))
  - expedite the review of a premarket submission or facility inspection, as appropriate, that could help mitigate or prevent a shortage (section 506J(f))

Amendment to Section 506J

The Consolidated Appropriations Act (FY23 Omnibus), signed into law on December 29th, 2022, amended section 506J of the FD&C Act

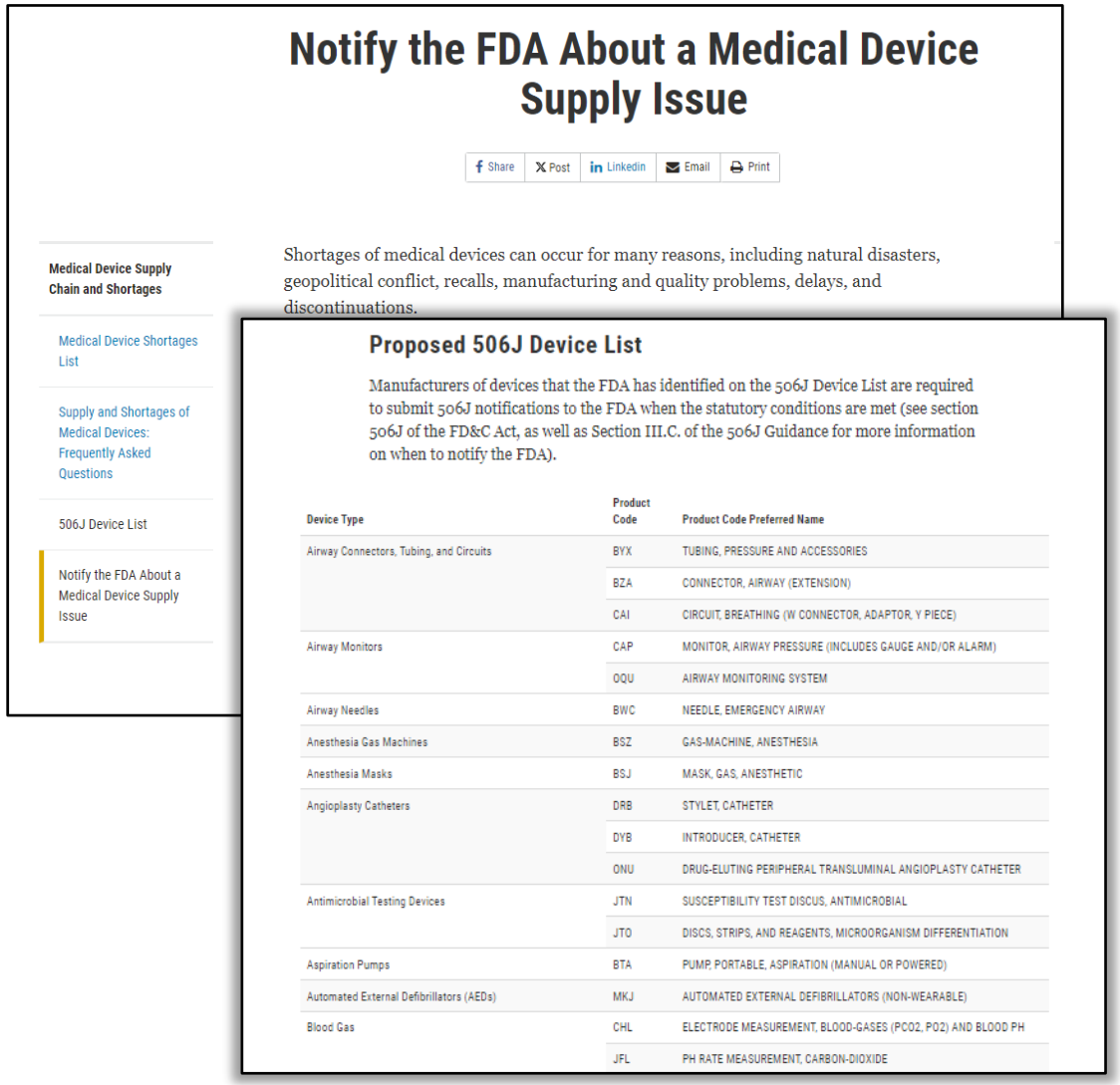
Directed FDA to issue draft guidance to facilitate voluntary notifications (FY23 Omnibus § 2514(b)) **and** issue or revise draft guidance regarding requirements under section 506J...

...guidance shall ***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 (FY23 Omnibus § 2514(c))

- Section 506J(h) makes explicit that FDA may receive voluntary notifications from manufacturers of certain devices outside of a public health emergency (PHE)
- The 506J Device List and draft guidance was required to be issued within one year of the enactment of the FY23 Omnibus (by December 29, 2023)

The 506J Device List

- When finalized, the 506J Device List is intended to assist manufacturers in providing timely notifications to the FDA
- The 506J Device List will reside on the FDA webpage: https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list
- The FDA expects that the list will evolve over time and the FDA intends to periodically reevaluate the list. Any revisions to the 506J Device List will follow the FDA's good guidance practices.



Notify the FDA About a Medical Device Supply Issue

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Medical Device Supply Chain and Shortages

- Medical Device Shortages List
- Supply and Shortages of Medical Devices: Frequently Asked Questions
- 506J Device List
- Notify the FDA About a Medical Device Supply Issue

Shortages of medical devices can occur for many reasons, including natural disasters, geopolitical conflict, recalls, manufacturing and quality problems, delays, and discontinuations.

Proposed 506J Device List

Manufacturers of devices that the FDA has identified on the 506J Device List are required to submit 506J notifications to the FDA when the statutory conditions are met (see section 506J of the FD&C Act, as well as Section III.C. of the 506J Guidance for more information on when to notify the FDA).

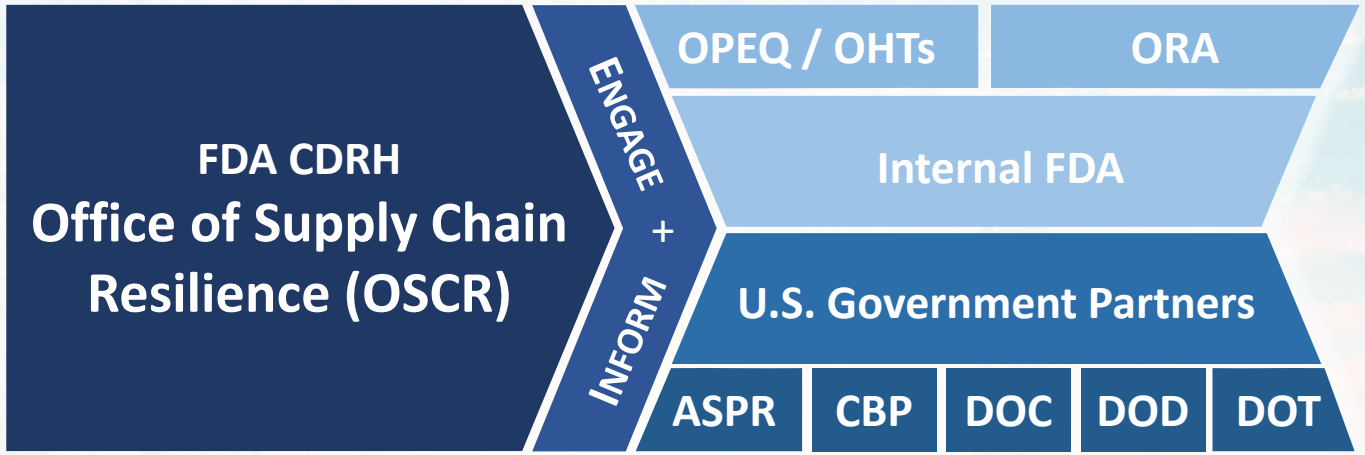
Device Type	Product Code	Product Code Preferred Name
Airway Connectors, Tubing, and Circuits	BYX	TUBING, PRESSURE AND ACCESSORIES
	BZA	CONNECTOR, AIRWAY (EXTENSION)
	CAI	CIRCUIT, BREATHING (W CONNECTOR, ADAPTOR, Y PIECE)
Airway Monitors	CAP	MONITOR, AIRWAY PRESSURE (INCLUDES GAUGE AND/OR ALARM)
	OQU	AIRWAY MONITORING SYSTEM
Airway Needles	BWC	NEEDLE, EMERGENCY AIRWAY
Anesthesia Gas Machines	BSZ	GAS-MACHINE, ANESTHESIA
Anesthesia Masks	BSJ	MASK, GAS, ANESTHETIC
Angioplasty Catheters	DRB	STYLET, CATHETER
	DYB	INTRODUCER, CATHETER
	ONU	DRUG-ELUTING PERIPHERAL TRANSLUMINAL ANGIOPLASTY CATHETER
Antimicrobial Testing Devices	JTN	SUSCEPTIBILITY TEST DISCUS, ANTIMICROBIAL
	JTO	DISCS, STRIPS, AND REAGENTS, MICROORGANISM DIFFERENTIATION
Aspiration Pumps	BTA	PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED)
Automated External Defibrillators (AEDs)	MKJ	AUTOMATED EXTERNAL DEFIBRILLATORS (NON-WEARABLE)
Blood Gas	CHL	ELECTRODE MEASUREMENT, BLOOD-GASES (PCO2, PO2) AND BLOOD PH
	JFL	PH RATE MEASUREMENT, CARBON-DIOXIDE

How Does CDRH Use 506J Notifications?

506J Notifications: What we do with this information

The Patient Impact Assessment identifies and informs prevention and mitigation strategies, in collaboration with FDA and other U.S. government partners

OSCR Serves as Liaison to U.S. Government Partners



Notable Examples:

- **Saline Flush Syringes (March 2022)**
- **Resin Shortages (Winter Storm Uri (February 2021))**

Example Prevention & Mitigation Strategies

Regulatory Mitigation Strategies:

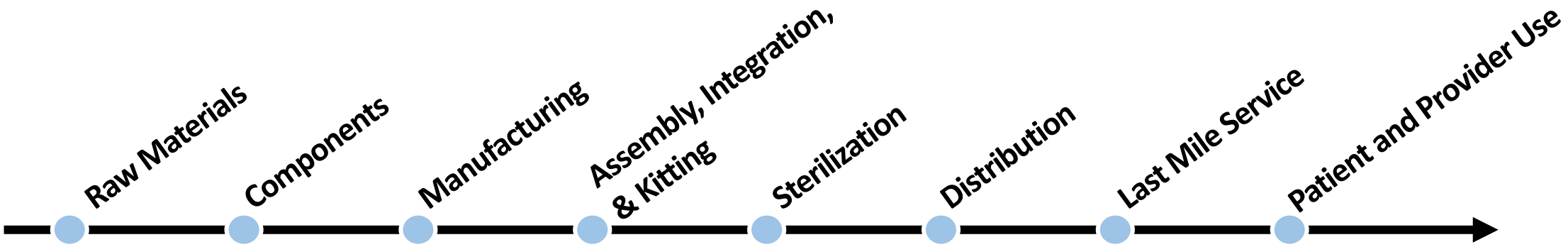
- Expedited premarket submissions
- Emergency Use Authorizations (EUAs)
- Regulatory Discretion
- Letters to Healthcare Providers (LHCP)

Non-Regulatory Mitigation Strategies:

- Actions by other US Government partners, including:
  - Transportation prioritization (Customs & Border; Department of Transportation)
  - Defense Production Act (DPA) Priority Ratings and priority request letters
  - Clearance through Customs and Border Protection (CBP)

Proactive Engagement Protects Patients

Notifications for devices included on this list will help prevent and mitigate shortages of critical devices needed for patient care in emergent medical situations



Before patient impacts

Greater ability to prevent patient impacts if the FDA receives notice of a supply chain interruption via 506J notification

After patient impacts

Limited ability to prevent impacts once patients and providers experience a shortage

Development of the Proposed 506J Device List

Development of the Proposed 506J Device List

The FDA followed a rigorous process to develop the proposed 506J Device List, based on criteria consistent with the language in section 506J and informed by lessons learned from previous supply chain disruptions and shortages

1. Compiled an initial list of devices (by product code)
2. Evaluated each product code against the statutory criteria outlined in section 506J
3. Considered device resiliency, characteristics, and the availability of suitable alternatives

Proposed 506J Device List

Statutory Criteria

Devices that were considered for inclusion on the proposed 506J Device List included those:

- **"that are critical to public health during a PHE, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery"** (section 506J(a)(1))

- In its deliberations, the FDA also considered:

  - Whether the device is used to diagnose, treat, monitor, or prevent a serious disease or medical condition;

  - 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

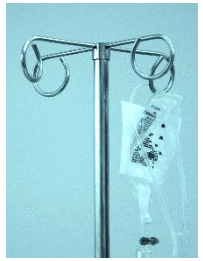
Additional Considerations

The FDA also considered characteristics of a device type and supply chain resiliency when developing the list

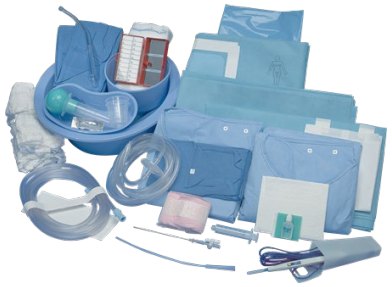
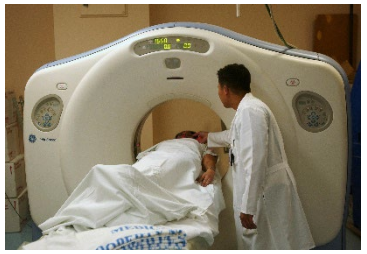
Examples:

- Are there specific characteristics of device types that make them more vulnerable or more resilient to sudden increases in demand or supply chain disruptions?
  - Single-use disposable vs. multi-patient reusable devices
  - Convenience kits
  - Capital equipment
- Market share, number of manufacturers, manufacturers' locations
- Known vulnerabilities in the supply of raw materials or components
- Knowledge gained from the FDA's experience with prior supply chain disruptions and the COVID-19 PHE

FDA Considerations – Specific Categories of Devices

Category	FDA Thinking
Single-Use Disposable Devices Examples: N95 respirators, masks, syringes & needles, catheters, PPE  	The FDA considers these devices **vulnerable to supply chain disruptions** and/or acute increases in demand and has included those that meet the statutory definition on the proposed 506J Device List. Acute increases in demand or disruptions in the availability of raw materials can quickly lead to shortages of single-use disposable devices and these shortages have impacted the ability to deliver patient care.
Multi-Patient Reusable Devices Examples: Hospital beds, personal assist mobility devices, IV poles, and stethoscopes  	The FDA considers 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)), these device types were not proposed for inclusion on the proposed 506J Device List.

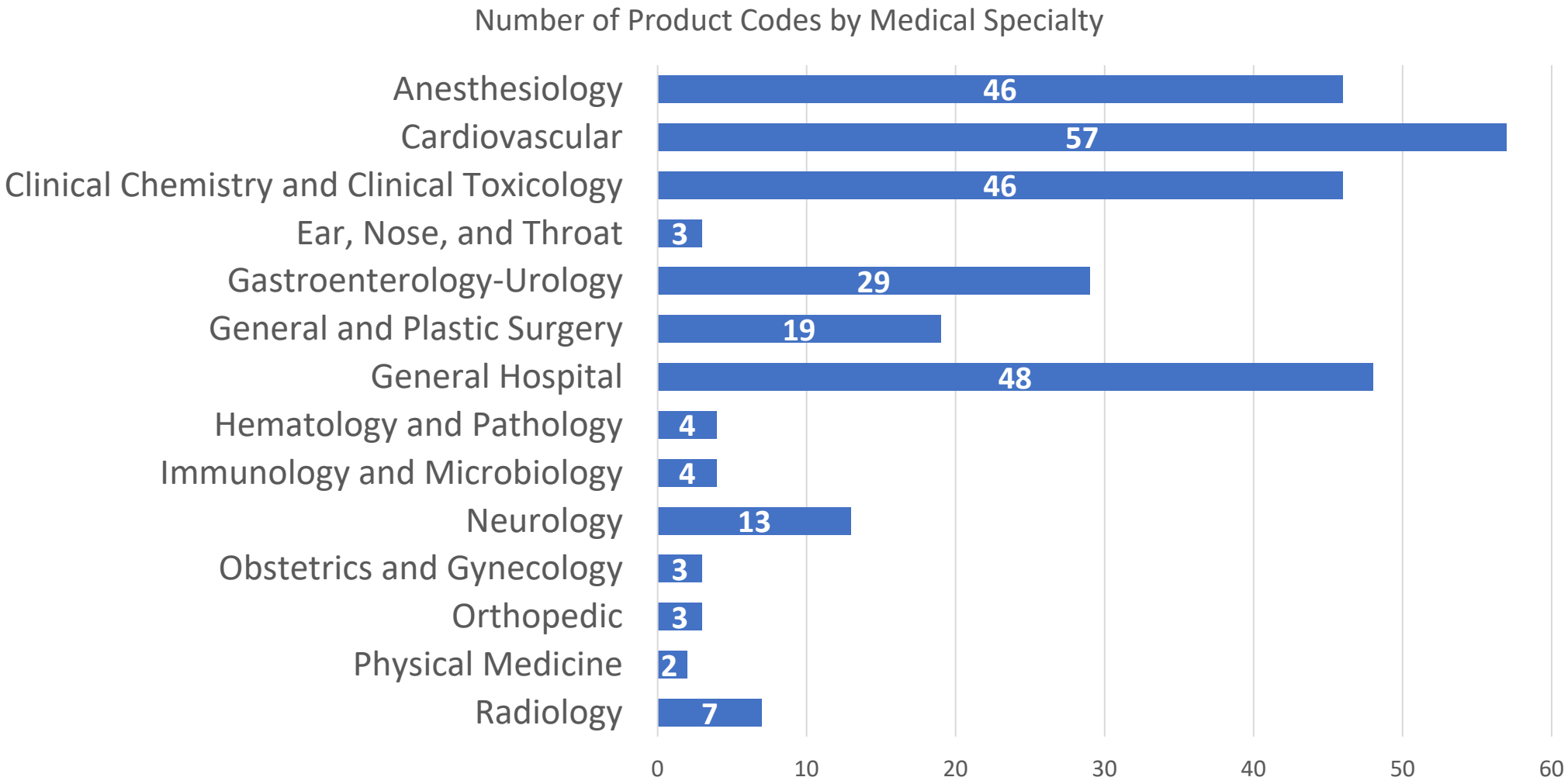
FDA Considerations – Specific Categories of Devices

Category	FDA Thinking
Convenience Kits Kits with two or more different medical devices packaged together 	In general, **convenience kits were not included** on the proposed 506J Device List. One kit (FCN - Urinary Drainage Collection Kit, For Indwelling Catheter) was included because of its clinical use and because its component parts are part of a closed-system.
Capital Equipment Examples: Ethylene Oxide Gas Sterilizers, plain X-ray systems, computed tomography (CT) scan and ultrasound systems 	Capital equipment deemed critical for supporting the continuity of healthcare delivery in the United States and necessary for diagnosing and treating patients in an emergent or emergency medical situation (e.g., trauma or CBRN event) was included on the proposed list. These devices are also potentially vulnerable to ongoing regulatory pressures and component shortages.

Proposed 506J Device List

Proposed 506J Device List by Medical Specialty

The majority of devices proposed for inclusion on the 506J Device List fall within the Cardiovascular, General Hospital, Anesthesiology, and Clinical Chemistry and Clinical Toxicology medical specialties

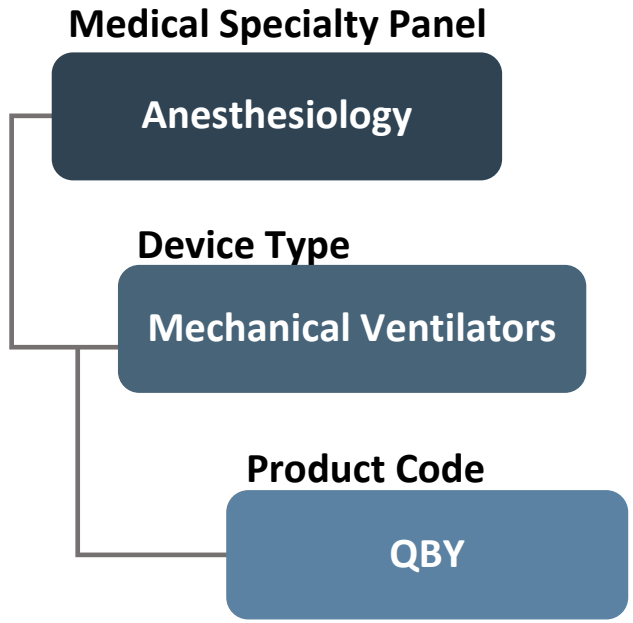


Organization of the Proposed 506J Device List

The proposed 506J Device List contains 284 product codes that can be organized under 14 medical specialty panels

- FDA has classified and described 1,700+ distinct types of devices in Title 21 of the Code of Federal Regulations (CFR) according to 16 medical specialty "panels" (21 CFR Parts 862-892)
- To facilitate the Panel's review, the proposed 506J Device List has been organized by Medical Specialty Panel.

- **Medical Specialty Panel:** Clinical area of the device according to the medical specialty "panels" defined in 21 CFR Parts 862-892
- **Device Type:** Group of devices with similar clinical use
- **Product Code:** Three-letter classification created by the FDA to assist in accurate identification and tracking of current medical devices and to allow for tracking of and easy reference to predicate device types



Proposed 506J Device List

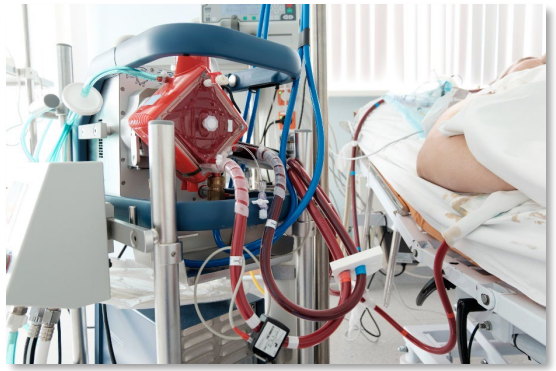
Anesthesiology; Ear, Nose, & Throat Panels

- Device types and product codes include those used to deliver anesthesia and those required for optimal oxygenation and ventilation
  - Mechanical ventilators and accessory devices
  - Anesthesia machines and accessory devices
    - Flow meters, gas analyzers
  - Oxygen Delivery Devices
    - Nasal cannulas, oxygen masks
- Devices used to visualize airways and facilitate intubation
  - Tracheostomy tubes
  - Bronchoscopes and accessories
- Devices used to maintain airway patency
  - Suction tubes & catheters (tonsil suction tube)

Proposed 506J Device List

Cardiovascular Panel

- Device types and product codes include those that:
  - Are required for maintaining adequate perfusion to the tissues and organs with oxygenated blood
  - Used to perform mechanical circulatory support
    - Extracorporeal membrane oxygenation (ECMO) cannulas, system, and blood pump, ventricular assist devices (VADs), and intra-aortic balloon pump system (IABP)
  - Used for physiological monitoring
    - Blood pressure systems and cuffs, electrocardiogram (ECG) system
  - Used to maintain vessel patency
    - Endovascular grafts, angioplasty catheters and stents
  - Used for analyzing and restoring the heart rhythm
    - Automated external defibrillators (AEDs)



Proposed 506J Device List

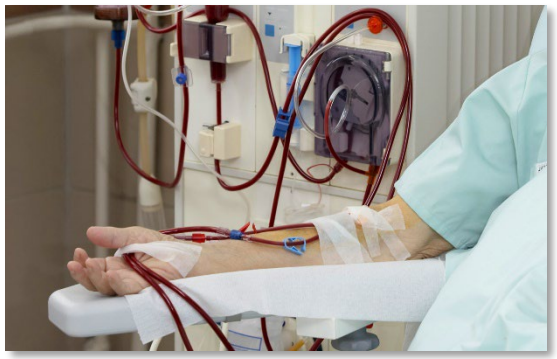
Clinical Chemistry and Clinical Toxicology Panel

- Clinical Chemistry and Clinical Toxicology Panels
  - Support specimen collection and testing of patient specimens
    - Vacuum collection bottles, sterile specimen containers, and newborn screening specimen collection paper
  - Analyze blood samples for biological markers and metabolic disturbances that may be present in critically ill patients
    - Cardiac enzymes and complete metabolic panel tests
  - Monitor and maintain glucose levels
    - Insulin pumps and glucose sensors

Proposed 506J Device List

Gastroenterology & Urology Panel

- Device types include those that are used for delivering life-sustaining and life-supporting treatment of patients with acute or chronic renal failure, as well as those with gastrointestinal disorders
  - Devices required to perform hemodialysis, peritoneal dialysis, kidney perfusion, and continuous renal replacement therapy
    - Femoral catheters, dialysate tubing, dialyzers, hemodialysis catheters, hemodialysis circuit accessories, and kidney perfusion systems
  - Gastrointestinal Devices
    - Endoscopes and accessory devices
    - Gastrointestinal (GI) stents
  - Urological Devices
    - Urinary catheters and related devices



Proposed 506J Device List

General and Plastic Surgery Panel

- Device types and product codes include those used in general surgeries, bleeding control, incision and wound closure, and wound care
  - General surgery and maintenance of a sterile surgical field
    - Aspiration pumps and surgical drapes
  - Control bleeding
    - Hemostatic agents, cautery devices, and tourniquets
  - Incision and wound closure
    - Sutures, clips, and appliers
  - Wound care
    - Gauze, tape, sponges, adhesive bandages, and dressings

Proposed 506J Device List

General Hospital Panel

- Product codes include those device types that are needed to support nutrition, fluid delivery, and other basic physiological functions
  - Devices used to gain vascular access and infuse drugs and/or fluids
    - Catheters, ports, syringes, needles, infusion pumps, IV containers, stopcocks, and suction catheters
  - Devices necessary to protect wearers from spread of infection or illness
    - N-95 public use respirators, non-sterile patient examination gloves, surgeon's gloves, masks, and gowns
  - Devices used to disinfect and sterilize medical devices
    - Disinfectants and disinfectors

Proposed 506J Device List

Hematology & Pathology; Immunology & Microbiology Panels

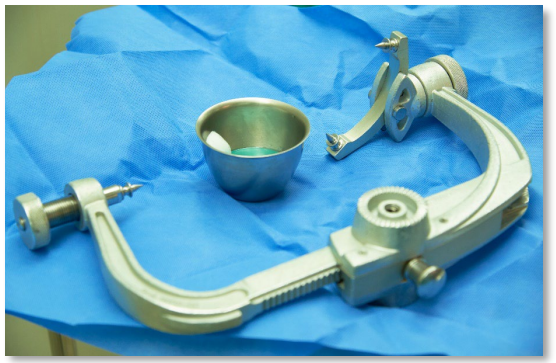
- Device types and product codes include those that are used to collect, transport, and analyze patient specimens to determine the presence of coagulation abnormalities as well as culture and identify microorganisms
- Device types include those that are used to:
  - Test for coagulation abnormalities
  - Collect and transport patient specimens
  - Culture and identify microorganisms
  - Test for antimicrobial sensitivities

Image Credit: Wikimedia

Proposed 506J Device List

Orthopedic; Physical Medicine; and Neurology Panels

- Device types include those used:
  - To perform orthopedic and neurosurgical surgeries and procedures
    - Head holders, aneurysm clips and appliers, drills, burrs, and trephines
    - Intervertebral fusion devices and pedicle screw systems
  - In physical medicine for spine stabilization
    - Orthoses (Cervical and Thoracic)
  - To measure intracranial pressure (ICP) and cerebral oxygen levels, as well as treat elevated ICP and intracranial blood clots
    - Central nervous system shunts, thrombus retriever, and cerebral oximeter



Proposed 506J Device List

Obstetrics and Gynecology and Radiology Panels

- Device types include those used for fetal monitoring and intrauterine dilation, as well as those used to perform diagnostic imaging
  - Fetal monitoring and intrauterine dilation
    - Fetal monitors and intrauterine tamponade balloon
  - Diagnostic imaging
    - Computed tomography (CT) scan, plain x-ray systems, and ultrasound systems and accessory devices

Feedback on the Proposed 506J Device List

Advisory Committee Meeting and Public Docket

Docket #FDA-2023-N-4807 closes March 6, 2024

FEDERAL REGISTER
The Daily Journal of the United States Government

Notice

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments-506J Device List

A Notice by the Food and Drug Administration on 11/17/2023

You are submitting an official comment to Regulations.gov.

Thank you for taking the time to create a comment. Your input is important.

Once you have filled in the required fields below you can preview and/or submit your comment to the Health and Human Services Department for review. All comments are considered public and will be posted online once the Health and Human Services Department has reviewed them.

You can view alternative ways to comment or you may also comment via Regulations.gov at https://www.regulations.gov/commenton/FDA-2023-N-4807-0001.

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SUPPORT

Comment Period Ends: **110 Days**

You are commenting on a Notice by the **Food and Drug Administration**

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—506J Device List

Write a Comment

Commenter's Checklist

Comment*

Start typing comment here...

5000

Questions to the Panel

Questions for Panel Consideration

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?**
    1. Single-use disposable vs. multi-patient reusable devices
    2. Convenience kits
    3. Capital equipment (e.g., imaging devices)

Q&A

Meeting Agenda

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9:00 a.m.	Call to Order Panel Introductions Conflict of Interest Statements
9:20 a.m.	Opening Remarks
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5:00 p.m.	Adjourn

Thank You