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US FDA Regulatory Overview for PPE

June 8, 2020

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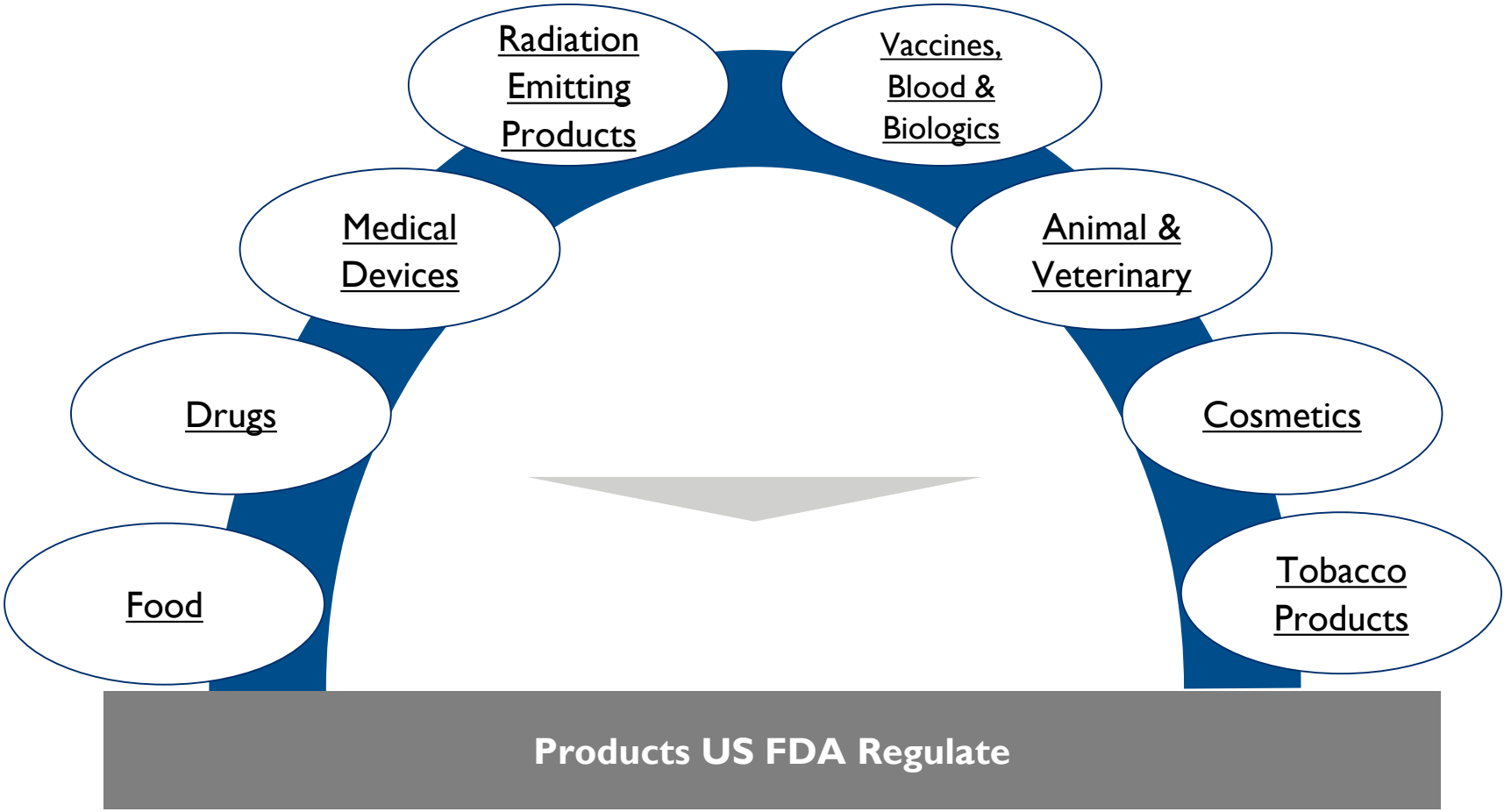
Agenda

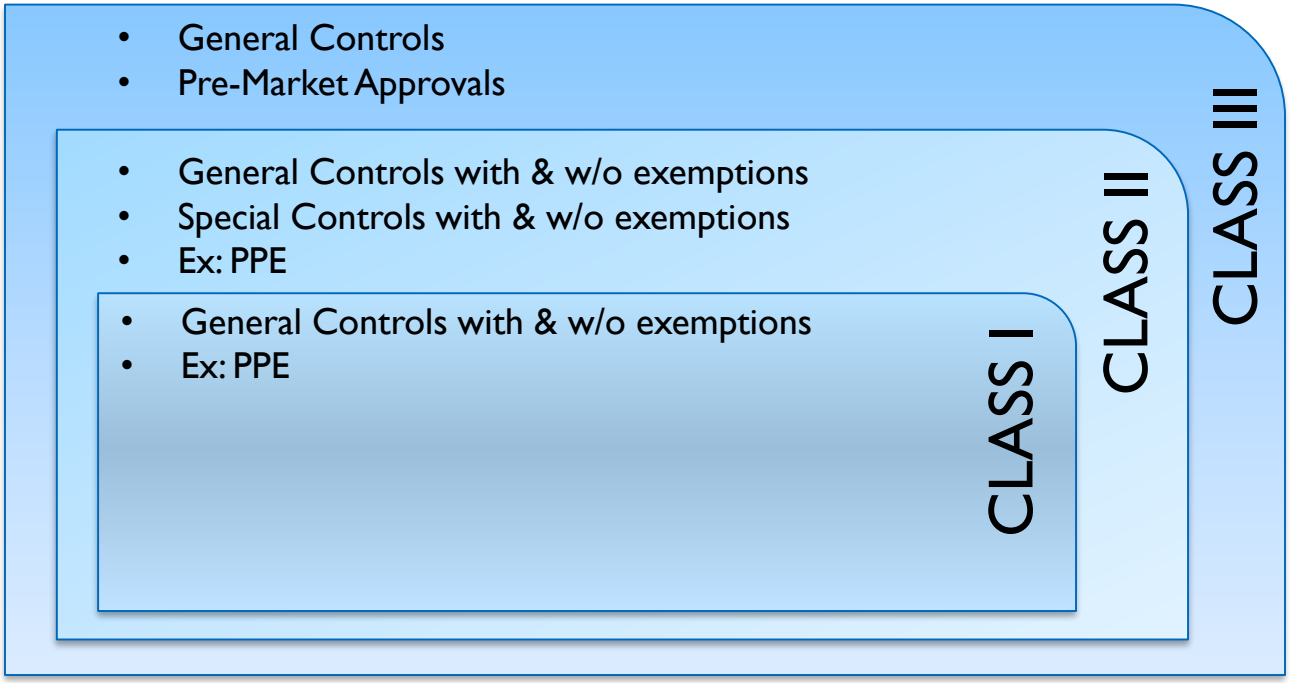
1. Overview of U.S. FDA
2. Device Classification
3. Emergency Use Authorization
4. COVID-19 Policy Responses
5. Higher Risk Devices: Emergency Use Authorization
6. Higher Risk Devices: Post Emergency Use Authorization
7. Questions & Answers

U.S. Food & Drug Administration (FDA)

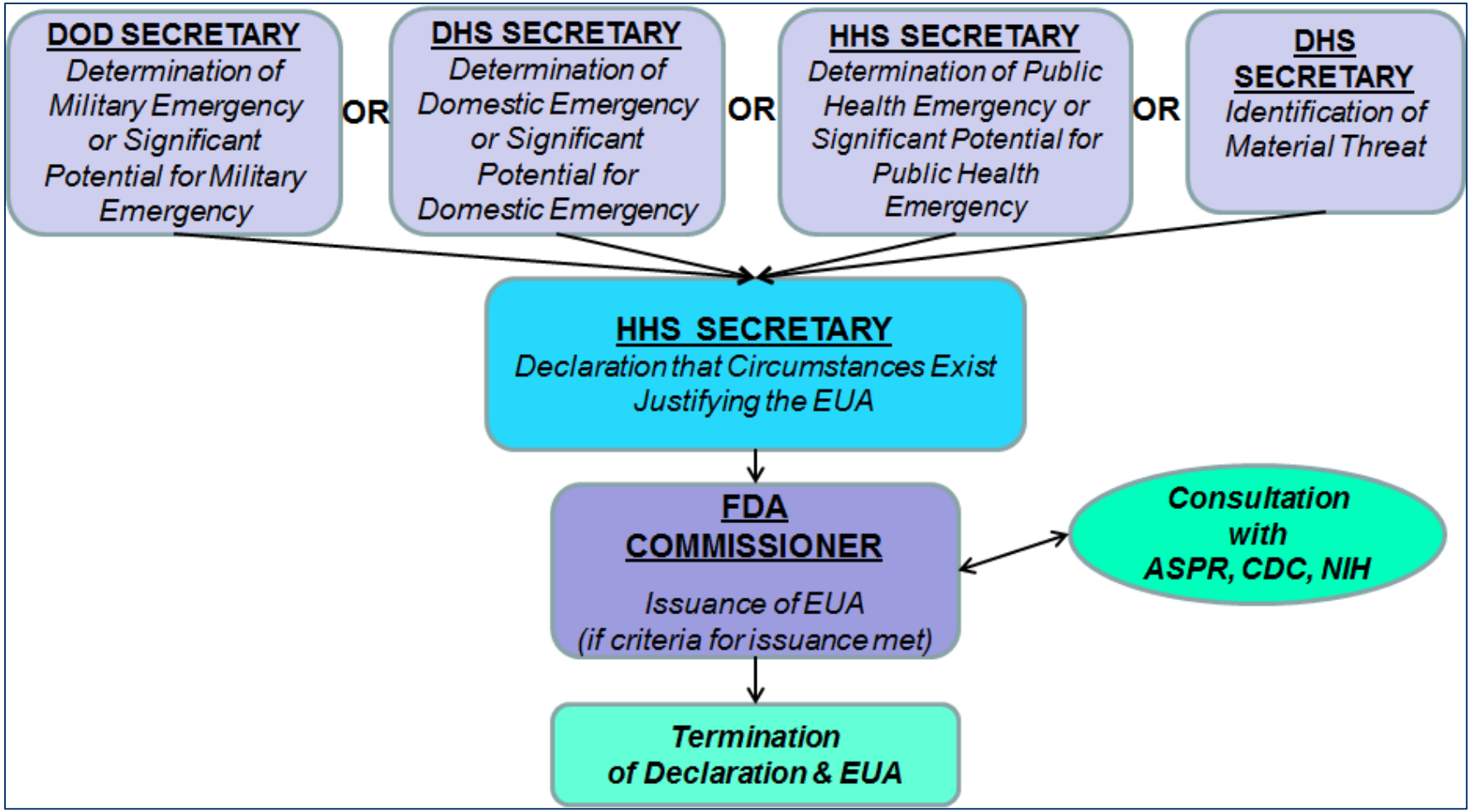


FDA Device Classification Overview

- The FDA categorizes medical devices into one of three classes – Class I, II, or III – based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.
- Class I devices generally pose the lowest risk to the patient and/or user and Class III devices pose the highest risk.
- Device classification depends on the *intended use* of the device and also upon *indications for use*.



Summary of Process for Emergency Use Authorization (EUA) Issuance



FAQs on Emergency Use Authorizations for Medical Devices During the COVID-19 Pandemic

1. During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.

2. Before the FDA can issue an EUA, the Secretary of Health and Human Services must make a declaration of emergency or threat justifying authorization of emergency use for a product.

3. When the emergency is over, the EUA declaration is terminated, and all EUAs issued based on that declaration will no longer remain in effect.

Note: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-during-covid-19-pandemic

US FDA Contacts for Medical Devices During the COVID-19 Pandemic

Industry Hotline:
COVID-19 Diagnostic Tests & Shortages
Content date: 05/22/2020

Phone: 1-888- INFO-FDA and choose option *

Hours: Monday-Friday: 8:00 a.m.-midnight ET. Weekends and holidays: 8:00 a.m.-8:00 p.m. ET.

Questions about EAU

Q: EAUs for in vitro diagnostic tests- COVID19DX@fda.hhs.gov

Q: EAUs for other devices, including PPE, respirators, ventilators- CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov

Enforcement Policy Questions

Q: Digital health, particularly digital health devices for psychiatric disorders- CDRH-COVID19-DigitalHealthForPsychiatricDisorders@fda.hhs.gov

Q: Gloves, gowns & other apparel- CDRH-COVID19-PPE@fda.hhs.gov

Q: Infusion Pumps- CDRH-COVID19-InfusionPumps@fda.hhs.gov

Q: Ophthalmic devices for remote assessment and monitoring- CDRH-COVID19-Ophthalmic@fda.hhs.gov

Q: Masks, including surgical masks & Respirators, including N95 and KN95 respirators- CDRH-COVID19-SurgicalMasks@fda.hhs.gov

Note: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/contacts-medical-devices-during-covid-19-pandemic

Personal Protective Equipment EUAs

- The U.S. FDA is issuing this Emergency Use Authorization (EUA) in response to concerns relating to insufficient supply and availability of gowns and other apparel for use by healthcare personnel (HCP) as personal protective equipment (PPE)
- **Scope of Authorization:**
  - Pursuant to Section 564(d)(1) of the Act, the scope of authorization is limited to the use of certain gowns and other apparel for use by HCP as PPE in healthcare settings in accordance with CDC recommendations to protect both HCP and patients from the transfer of SARS-CoV-2 in low or minimal risk level situations to prevent the spread of COVID19.
  - This use is consistent with regulation of products under 21 CFR 878.4040 listed in the below table and types of gowns & other apparel included in the scope of this EAU are those that are identified in the "Device Type" column.

Classification Regulation	Device Type	Product Code	Class
21 CFR 878.4040	Conductive shoe and shoe cover	BWP	I (exempt)
21 CFR 878.4040	Operating-room shoes	FXW	I (exempt)
21 CFR 878.4040	Operating-room shoes	LYU	I (exempt)
21 CFR 878.4040	Non-surgical isolation gown	OEA	I (exempt)
21 CFR 878.4040	Operating-room shoe cover	FXP	I (exempt)
21 CFR 878.4040	Surgical helmet	FXZ	I (exempt)
21 CFR 878.4040	Surgical cap	FYF	I (exempt)

05/22/20 EUA issued for Gowns and other apparel: https://www.fda.gov/media/138326/download

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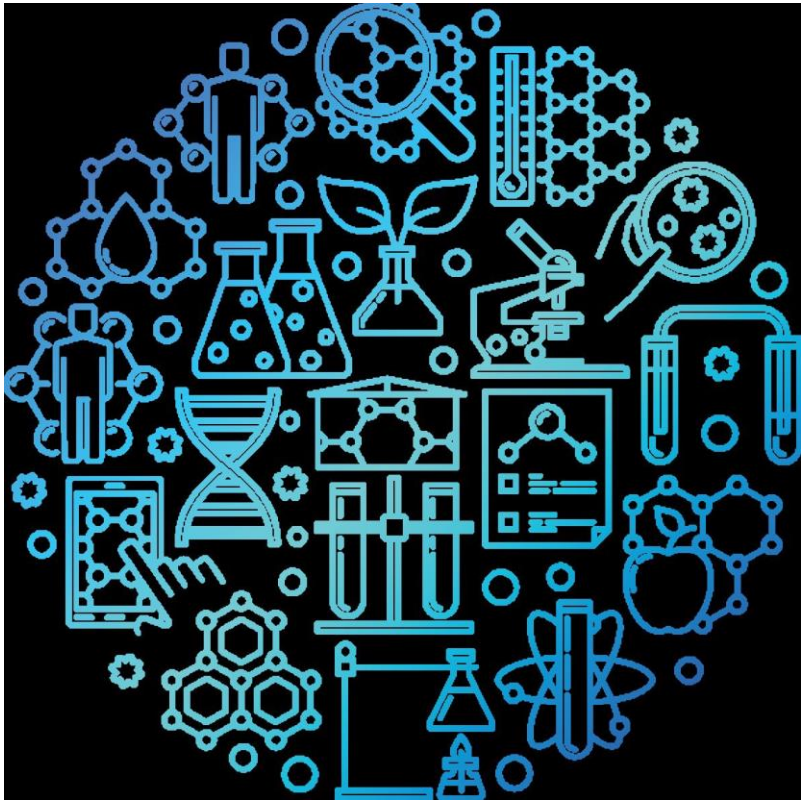

COVID-19 Policy Responses

COVID-19 policy response timeline at glance

1

Coronavirus Preparedness & Response Supplemental Act
Enacted March 6th 2020

- $8.3 billion in emergency appropriations for COVID-19 response — $6.7 billion designated for domestic response and $1.6 billion for international humanitarian response.
- Majority ($6.2 billion) goes to the Department of Health and Human Services (JHHS) in the areas of vaccine development, medical supplies, infectious disease response, and public health services to isolated and economically or medically vulnerable

https://congress.gov/bill/116th-congress/house-bill/6074/text

2

Families First Coronavirus Response Act
Enacted March 17th 2020

- Legislation mandates free coronavirus testing, establishes paid sick leave, enhances unemployment insurance, expands food security initiatives, and increase federal Medicaid funding
- Includes $1 billion in 2020 for emergency grants to states for activities related to processing and paying unemployment insurance (UI) benefits

https://docs.house.gov/billsthisweek/20200309/BILLS-116hr6201-SUS.pdf

3 4

Coronavirus Aid, Relief, and Economic Security Act (CARES Act)
Enacted March 27th 2020

- President Trump signed into law a **$2 trillion** legislative package to protect the health and well-being of Americans during the COVID- 19 pandemic and provide a boost to the American health care system, including **$340 billion in emergency appropriations** to Federal agencies serving the needs of the health care sector during the crisis.
- The majority of provisions in the bill are meant to last the duration of the emergency period which lasts as long as there is a public health emergency declared by the President

Source: World Health Organization; The New York Times; The Official White House

Summary of the CARES Act

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

Health care system & economic enhancement and stabilization

Establishes mechanisms to fund an array of programs, including direct payments to Americans, an expansion of unemployment insurance, billions of dollars in aid to large and small businesses, and a new wave of funding/programming for the health care industry.

Emergency appropriations for COVID response and operations

Appropriates billions of dollars in immediate aid for the health care system, including funding for hospitals, research, treatment, surveillance, disaster relief and the Strategic National Stockpile to raise supplies of ventilators, masks and other equipment.

Providers/Hospitals

Deliver an immediate stimulus and relief assistance to providers treating patients with COVID-19.

Coverage

Establish guidelines for the testing, prevention, treatment, and vaccination of patients.

Drugs & Devices

Address mechanisms to alleviate supply shortages and increase speed to market in select cases.

Other Relief

Begins to establish relief, recovery, and future response mechanisms within public health programs.

Deeper Dive: MedTech supply chain provisions of the CARES Act

Expands the Strategic National Stockpile to include personal protective equipment and supplies

Reporting to FDA of supply disruption for devices and drugs critical to public health during a public health emergency

Requires the **National Academies to study the manufacturing supply chain** and provide Congress with recommendation to strengthen

Permanently extend liability immunity to manufacturers of respiratory protective devices (including masks and respirators) during a public health emergency

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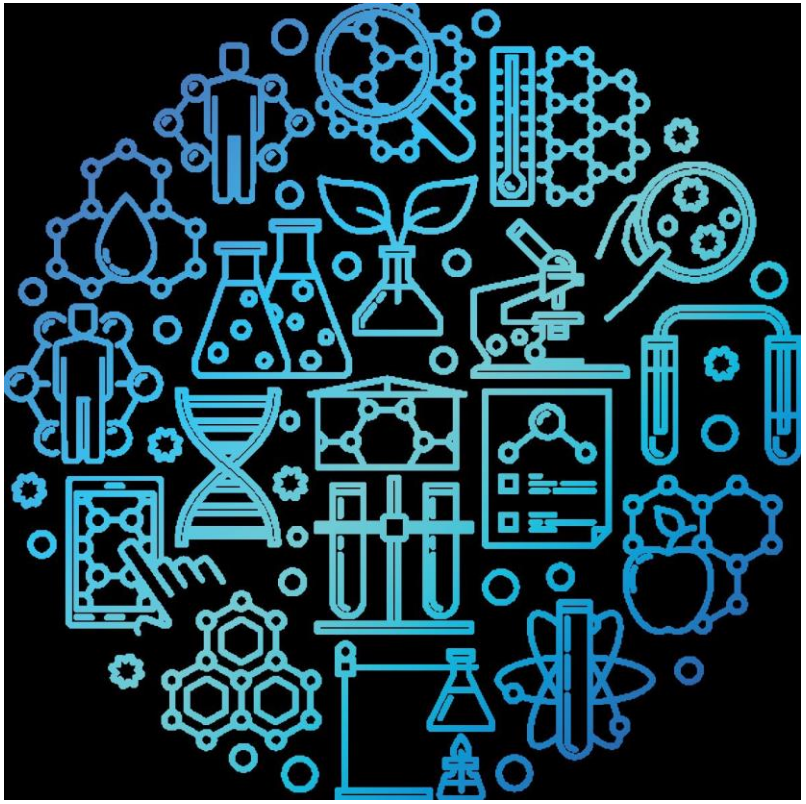


HIGHER RISK DEVICES:
Emergency Use Authorization

Our understanding

01

The Sri Lanka textile industry is already manufacturing and exporting to the United States low risk Class I devices, such as non-surgical isolation and non-protective face masks.
.

02

The industry is interested in manufacturing higher risk Personal Protective Equipment, specifically surgical masks and Filtering Facepiece Respirators (FFR), e.g. N95 respirators, for export to the US during the Emergency Use Authorization period as well as after the authorization period ends.

03

The industry wants to understand what actions are necessary in order to be able to export these devices to the US both during and after the authorization period.

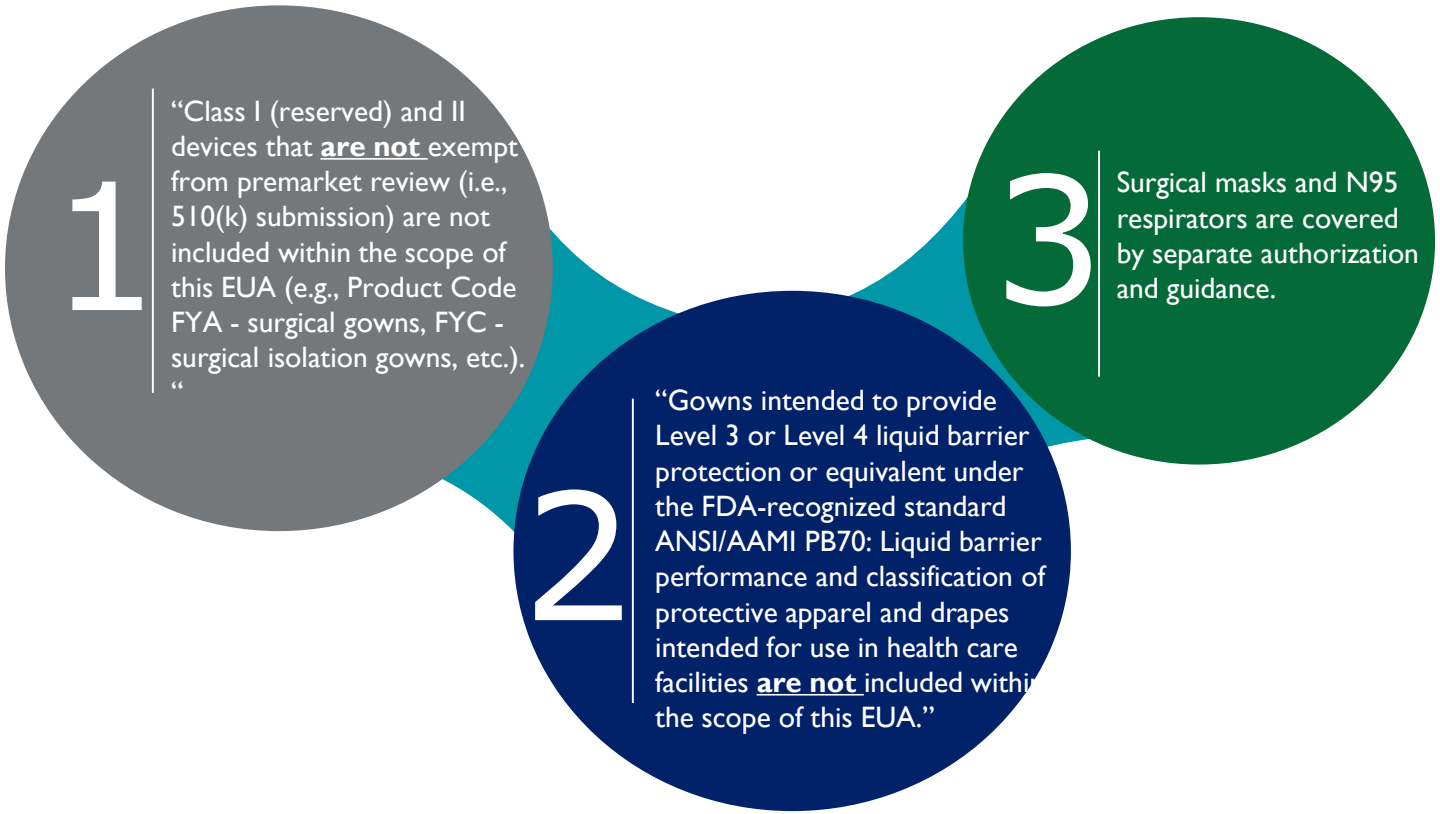
04

Therefore, the focus of this section will be on the requirements for surgical face masks, N95 respirators and gowns. However, the same general requirements apply for other moderate risk personal protective equipment.

What is normally required to commercially sell a Class II medical device in the US (e.g. Surgical Face Mask, N95 Respirator)?

- Submit a 510(k) to the US FDA for review and clearance ($11,594 FY20)
- Operate under a Quality Management System (QMS) that complies with the requirements of 21 CFR 820 and associated regulations
- Have a process for complying with Medical Device Reporting requirements under 21 CFR 803
- Have a process for complying with the requirements of 21 CFR 806 Reports of Corrective Actions and Removals (Recalls)
- Meet Unique Device Identifier (UDI) requirements
- Establishment Register and Device List ($5,236 in FY20)
- Obtain a US Agent
- Receive Clearance to Market letter from FDA for the device.

What products are not covered by the PPE EUA?



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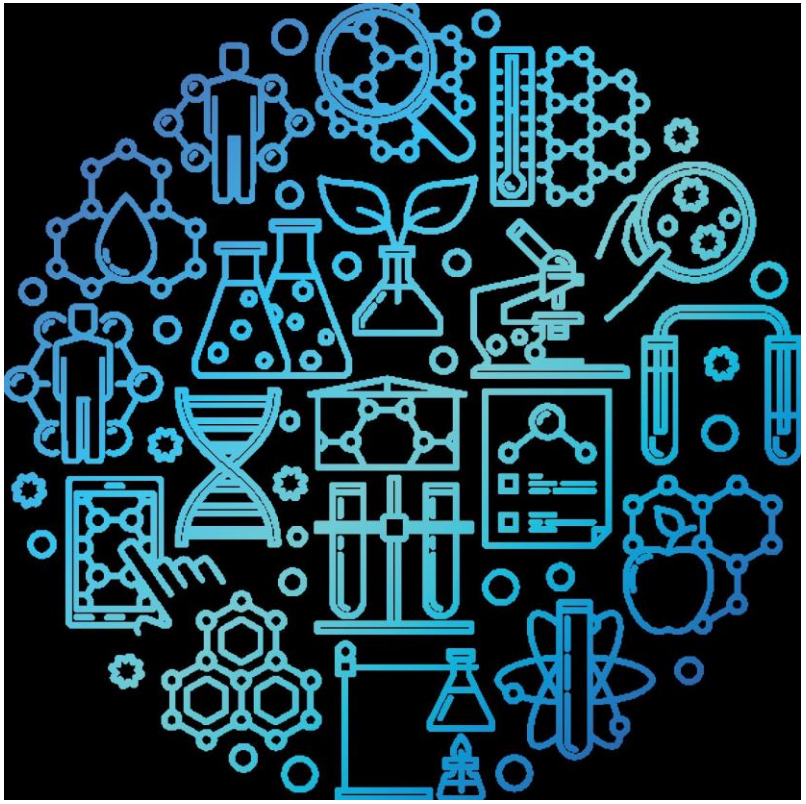


Masks and Respirators

Documents relevant to Surgical Masks and N95 Respirators

- Emergency Use Authorization Letter To: Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece , 28 March 2020 – only applies to devices approved in certain countries
- Emergency Use Authorization Letter To: Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, 07 May 2020 – only applies to approved deices from China
- Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) - Public Health Emergency (Revised) - Guidance for Industry and Food and Drug Administration Staff - May 2020 - includes section for unapproved devices and new manufacturers

"FDA is interested in interacting with manufacturers on additional device-specific EUAs. This may include manufacturers of masks and respirators that are not currently legally marketed in the US as well as manufacturers who have not previously manufactured masks or respirators with capabilities to increase supply of these devices."

Products in scope of the guidance

Classification Regulation	Device Type	Product Code
21 CFR 878.4040	Mask, Surgical	FXX
	Pediatric/Child Facemask	OXZ
	Accessory, Surgical Apparel (Face Shield)	LYU
	Surgical mask with antimicrobial/antiviral agent	OUK
	Respirator, Surgical	MSH
	N95 Respirator with Antimicrobial/Antiviral Agent	ONT
21 CFR 880.6260	N95 Respirator with Antimicrobial/Antiviral Agent for Use by the General Public in Public Health Medical Emergencies	ORW
21 CFR 880.6260	Respirator, N95, for Use by the General Public in Public Health Medical Emergencies	NZJ

Products Not in scope of the guidance

Classification Regulation	Device Type	Product Code
21 CFR 868.5450	Humidifier, Respiratory Mask	OBN
	Humidifier, Respiratory Gas	BTT
21 CFR 868.5550	Mask, Anesthetic, Gas	BSJ
21 CFR 868.5580	Mask, Oxygen	BYG
21 CFR 868.5600	Mask, Oxygen, Low Concentration, Venturi	BYG
21 CFR 868.5570	Mask, Oxygen, Non-Rebreathing	KGB
21 CFR 868.5905	Resuscitator, Manual, Non Self-Inflating	NHK
	Mask, Ventilator, Non-Continuous, Reprocessed	NMC
21 CFR 868.5560	Strap, Head, Gas Mask	BTK

Definitions in the Guidance

1

Face Mask

A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. Face masks are for use by the general public and HCP only as source control in accordance with CDC recommendations.

2

Face Shield

A face shield is a device used to protect the user's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. Generally, a face shield is situated at the crown of the head and is constructed with plastic to cover the user's eyes and face.

3

Surgical Mask

A mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests.

4

Filtering Facepiece Respirator

A filtering facepiece respirator (FFR) is a device that is a disposable half-face-piece 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.

Definitions in the Guidance continued

6

N95 Respirator

A disposable half-mask filtering facepiece respirator (FFR) that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.

7

NIOSH Approved N95 Respirator

An N95 respirator, approved by NIOSH that meets filtration efficiency level per 42 CFR 84.181. NIOSH - National Institute for Occupational Safety and Health – part of Centers for Disease Control (CDC) – conducts testing and issues standards related to disease prevention

8

Surgical N95 Respirator

A disposable FFR used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181. A surgical N95 respirator is regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.

Authorization requirements vary in the guidance depending on the intended use of the device

- Face Masks, Face Shields, and N95 Respirators **NOT** Intended for a Medical Purpose
- Face Masks Intended for a Medical Purpose that are **NOT** Intended to Provide Liquid Barrier Protection
- Face Shields Intended for a Medical Purpose
- Surgical Masks Intended to Provide Liquid Barrier Protection
- Alternatives When FDA-Cleared or NIOSH-Approved N95 Respirators are Not Available

Under the EUA and Guidance the following exemptions are made for all categories of devices in scope

For the duration of the declared public health emergency, FDA does not intend to object to the distribution and use of surgical masks without compliance with the following regulatory requirements where the surgical mask does not create an undue risk in light of the public health emergency:

- Prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,
- Registration and Listing requirements in 21 CFR 807,
- Quality System Regulation requirements in 21 CFR 820,
- Reports of Corrections and Removals in 21 CFR Part 806, and
- Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.

Deeper Dive: Face Masks, Face Shields, and N95 Respirators NOT Intended for a medical purpose

For face masks, face shields, and FFRs that are marketed to the general public for general, **non-medical** purposes, such as use in construction and other industrial applications that are **not** intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, FDA device marketing authorization is **not** required, and all the other requirements of the FD&C Act do **not** apply to manufacturers, importers, and distributors of these products.

Such products cannot:

- Be labeled or otherwise intended for use by a HCP;
- Be labeled or otherwise for use in a health care facility or environment; and
- Cannot include any drugs, biologics, or anti-microbial/anti-viral agents.

Deeper Dive: Face Masks intended for a medical purpose that are NOT intended to provide liquid barrier protection

FDA currently believes such devices would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a face mask (as opposed to a surgical mask or FFR) and includes a list of the body contacting materials (which does not include any drugs or biologics);
- The product includes labeling that makes recommendations that would reduce sufficiently the risk of use, for example, recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; and
- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses and does not include particulate filtration claims.

Deeper Dive: Face Shields intended for a medical purpose

FDA currently believes such devices would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a face shield and includes a list of the body contacting materials (which does not include any drugs, or biologics);
- The face shield does not contain any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);
- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses, or for radiation protection.

Deeper Dive: Surgical Masks intended to provide liquid barrier protection

FDA currently believes such devices would not create such an undue risk where:

- The product meets fluid resistance testing (liquid barrier performance) consistent with standard ASTM F186218 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);
- The product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);
- The product includes labeling that accurately describes the product as a surgical mask and includes a list of the body contacting materials (which does not include any drugs or biologics); and
- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses and does not include particulate filtration claims.

Process to pursue an EUA under the guidance

- For face mask manufacturers who have not previously been engaged in medical device manufacturing but with capabilities to increase supply of these devices:
- Send the following information in an email to: CDRH-COVID19-SurgicalMasks@fda.hhs.gov that describes "their process and approach."
- In order to provide the strongest request to FDA, consider:
  - Testing for compliance with relevant standard, e.g. for N95: NIOSH TEB-APR-STP-0059, Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators Standard Test Procedure (STP) https://wwwn.cdc.gov/PPEInfo/Standards/Info/TEBAPRSTP0059
  - Develop relevant written procedures, e.g. MDR,
  - Provide proper labeling

FDA Website for Device Classification and Testing

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

Product Classification

FDA Home › Medical Devices › Databases

New Search | Back to Search Results

Device	Mask, Surgical
Regulation Description	Surgical apparel.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General Hospital
Product Code	FXX
Premarket Review	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(k)
Regulation Number	878.4040
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Recognized Consensus Standards

- 6-254 ASTM F2100-11 (Reapproved 2018)
  Standard Specification for Performance of Materials Used in Medical Face Masks
- 6-335 ASTM F2101-14
  Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- 6-406 ASTM F1862/F1862M-17
  Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- 6-425 ASTM F2100-19
  Standard Specification for Performance of Materials Used in Medical Face Masks
- 6-427 ASTM F2101-19
  Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

- Eligible for *Accredited Persons Program*

Process under the EUA continued

Utilize requirements for current manufacturers. Include:

01

General information such as your contact information, name and place of business, email address, and contact information for a U.S. agent (if any) in addition to general information about the device such as the proprietary or brand name, model number, and marketing authorization in your country (or region).

02

- A copy of product labelling
- Whether the device currently has marketing authorization in another regulatory jurisdiction *(including certification number, if available)*.

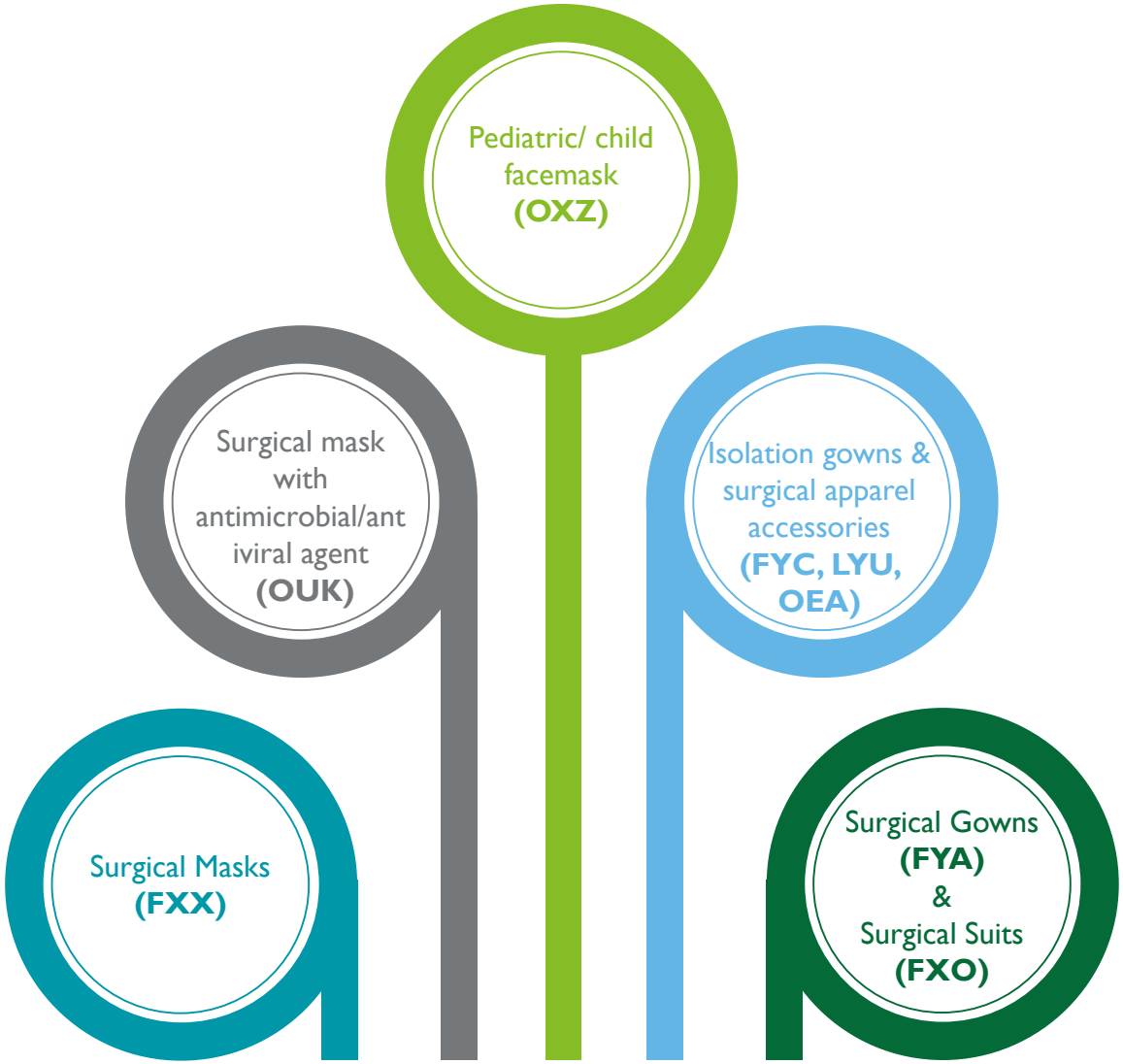
03

Whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes* or an equivalent quality system and the manufacturer or importer has documentation of such.

04

Description of testing conducted on the device, including any standards met, such as liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate. For surgical N95 respirators, FDA recommends including fluid resistance testing (liquid barrier performance).

Example email content from FDA FAQ



FDA website: **FAQs on Shortages of Surgical Masks and Gowns During the COVID-19 Pandemic**
https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns-during-covid-19-pandemic

Example email content

The FDA is interested in hearing from manufacturers who may be able to help mitigate potential shortages of the above product codes by increasing U.S. availability of such devices. These manufacturers may email the FDA at deviceshortages@fda.hhs.gov. This closely monitored email account has proven to be a valuable resource to help the FDA mitigate potential supply chain disruptions.

To facilitate a rapid response to your email, please see an example of information the FDA would find helpful to have initially:

- **Subject of the email:** "Product Codes XXX, Shortage Mitigation Options for FDA Engagement," where XXX represents the product code(s).
- **Body of the email:**
  - Describe the affected product or products which may include the brand name, model number, 510(k) number, etc.
  - Describe the proposed mitigation approach.
  - Identify what you are interested in discussing with FDA, such as:
  - Expedited review of a premarket submission, or
  - Expedited review of a manufacturing site change if you are a class III device manufacturer, or
  - Information about importing certain products.

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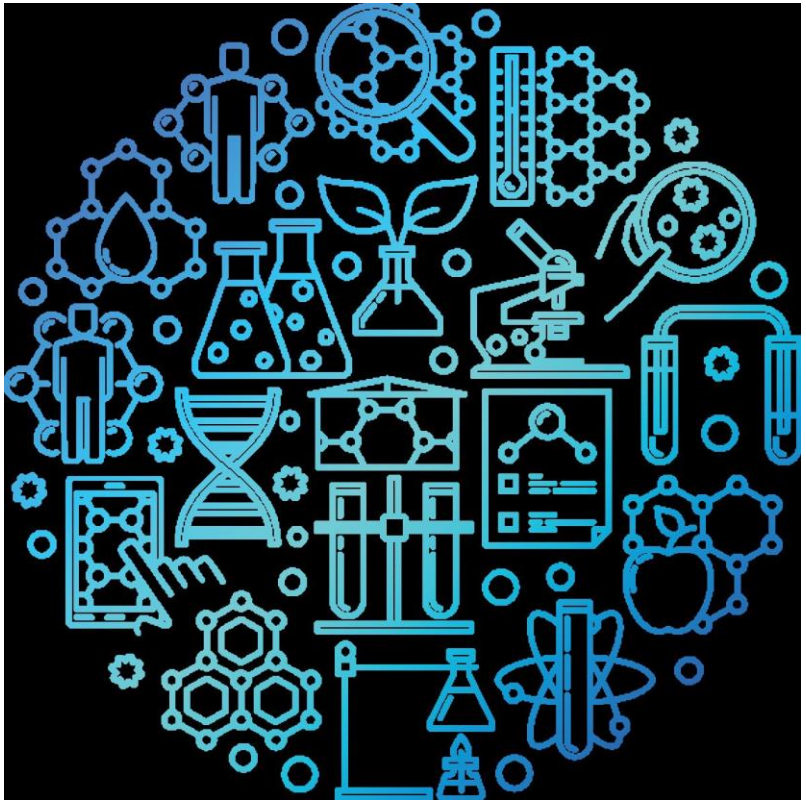


Gowns

Documents relevant to Gowns

- Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff - March 2020
- **Products in Scope**

Classification Regulation	Device Type	Product Code	Class
21 CFR 878.4040	Conductive Shoe and Shoe Cover	BWP	I (exempt)
21 CFR 878.4040	Operating-Room Shoes	FXW	I (exempt)
21 CFR 878.4040	Surgical Apparel Accessory	LYU	I (exempt)
21 CFR 878.4040	Non-surgical isolation gowns	OEA	I (exempt)
21 CFR 878.4040	Surgical suits	FXO	I (exempt)
21 CFR 878.4040	Operating-room shoe covers	FXP	I (exempt)
21 CFR 878.4040	Surgical helmets	FXZ	I (exempt)
21 CFR 878.4040	Surgical dress	FYE	I (exempt)
21 CFR 878.4040	Surgical caps	FYF	I (exempt)
21 CFR 878.4040	Surgical gown/toga	FYA	II
21 CFR 878.4040	Patient gown	FYB	II
21 CFR 878.4040	Surgical isolation gown	FYC	II
21 CFR 878.4040	Surgical hood	FXY	II

Authorization requirements vary in the guidance depending on the intended use of the device

- Gowns and Other Apparel Not Intended for a Medical Purpose
  - These are not medical devices
- Non-surgical Gowns and Minimal-to-Low Barrier Protection Surgical Apparel
  - ANSI/AAMI PB7011, 12 Level 1 protection or equivalent; or
  - ANSI/AAMI PB70 Level 2 protection or equivalent.
- Moderate-to-High Barrier Protection Surgical Gowns
  - ANSI/AAMI PB70 Level 3 protection (https://wwwn.cdc.gov/PPEInfo/Standards/Info/ANSI/AAMIPB70Class3) or equivalent; or
  - ANSI/AAMI PB70 Level 4 protection or equivalent.

Non-surgical Gowns and Minimal-to-Low Barrier Protection Surgical Apparel

When evaluating whether a gown under 21 CFR 878.4040(b) is not a "surgical gown," FDA will consider whether:

- it is labeled as a gown other than a surgical gown (e.g., isolation gown);
- it is not described in its labeling as a surgical gown; and
- it includes statements relating to barrier protection, and such statements are for only minimal or low barrier protection *(e.g., ANSI/AAMI PB70 barrier protection Level 1 or 2)*.

Under the Guidance the following exemptions are made for non-surgical gowns

FDA does not intend to object to the distribution and use of gowns not intended for use as "surgical gowns" and other low-to-minimal barrier protection surgical apparel that does not comply with the following regulatory requirements where the gowns and apparel do not create an undue risk in light of the public health emergency:

- Prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, (Note: these devices are Class I exempt and do not normally require a 510(k))
- Registration and Listing requirements in 21 CFR 807,
- Quality System Regulation requirements in 21 CFR 820,
- Reports of Corrections and Removals in 21 CFR Part 806, and
- Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.

Labeling requirements under the guidance for non-surgical gowns

- FDA currently believes such devices would not create such an undue risk where:
- The product includes labeling that accurately describes the product as a "gown," or "toga," or other apparel (as opposed to a "surgical gown," or "surgical toga") and includes a list of the body contacting materials (which does not include any drugs or biologics);
- The product includes labeling that makes recommendations that would reduce sufficiently the risk of use, for example, recommendations against: use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected, use in a clinical setting where Level 3 or 4 protection is warranted, and use in the presence of high intensity heat source or flammable gas; and
- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses.

Moderate-to-High Barrier Protection Surgical Gowns

When evaluating the classification of a gown under 21 CFR 878.4040(b), per FDA guidance, FDA will consider whether:

- it is labeled as such;
- it is described as such in its labeling; and/or
- it has statements relating to moderate or high-level barrier protection;
- it has statements that it is intended for use during sterile procedures.

An example of devices FDA considers to be "surgical gowns" includes gowns that are intended for use in health care settings requiring moderate or high liquid barrier protection levels (e.g., ANSI/AAMI PB70 barrier protection Level 3 or 4) and 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, bodily fluids, and particulate material in moderate- or high-risk situations

Under the Guidance the following exemptions are made for moderate-to-high barrier protection surgical gowns

FDA does not intend to object to the distribution and use of ANSI/AAMI PB70 Level 3 moderate-to-high barrier protection surgical gowns that do not comply with the following regulatory requirements, where such surgical gowns do not create an undue risk in light of the public health emergency:

- Prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,
- Registration and Listing requirements in 21 CFR 807,
- Reports of Corrections and Removals in 21 CFR Part 806, and
- Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.

These devices are NOT exempt from the Quality System requirements in 21 CFR 820, so a complete quality system is required in order to distribute them in the US.

Requirements under the guidance for moderate-to-high barrier protection surgical gowns

FDA currently believes such devices would not create an undue risk where, the product:

- Meets liquid barrier protection at Level 3 or higher, consistent with ANSI/AAMI PB70 for the critical zone areas;
- Meets the Class I or Class II flammability standard per 16 CFR Part 1610; and
- Has been demonstrated to be sterile if intended for use in surgical settings.
- The product includes labeling that accurately describes the product's sterility status (sterile or non-sterile), including any sterilization method used, barrier protection as Level 3, flammability classification (Class I or Class II), and a list of the body contacting materials;
- The product includes labeling with general statements and makes recommendations that would sufficiently reduce the risk of use, for example, a general statement about devices that have not been cleared by FDA, recommendations against use when FDA-cleared surgical gowns are available, and recommendations against use of non-sterile products in surgical settings; and
- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection; uses for infection prevention or reduction; or is labeled as having ANSI/AAMI PB70 Level 4 liquid barrier protection.

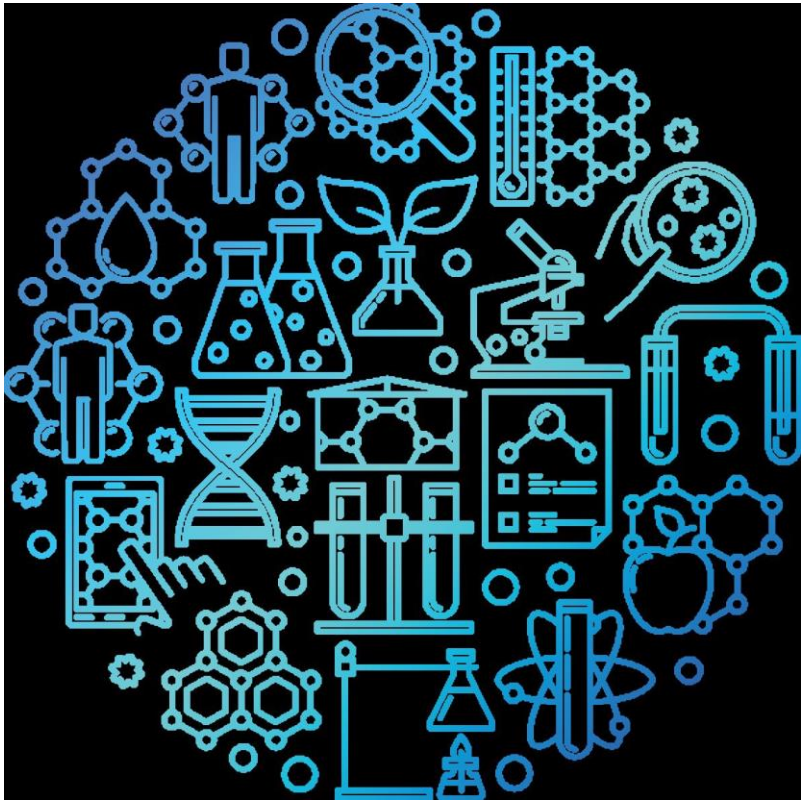
Process to pursue under the guidance

- The guidance does not require the submission of an email to FDA in order to receive authorization to commercially distribute products covered under the guidance, HOWEVER…..
- It would be prudent to notify FDA in order to let the Agency, as it may avoid issues at the Port of entry and once product is in distribution. Also, some purchasers may request some form of written authorization from FDA. So,
- Follow the same email approach as detailed for surgical masks and respirators
- For surgical gowns it will also be necessary to establish a full quality system in compliance with the requirements of 21 CFR 820, BEFORE commercially distributing these products in the US.

In conclusion

- Identify the appropriate product code for your product
- Get it tested to the necessary standard in an accredited lab
- Develop the necessary SOPs (e.g. MDR)
- Prepare an email in the FDA suggested format
- Provide all the necessary information
- Be prepared to have a discussion with FDA about your request
- Use sound, scientific and technical rationale for your position
- Address any FDA questions or requests
- Once you receive your authorization, begin shipping
- While not explicitly requested, it might be a good idea to retain a US Agent so someone in the US can respond to FDA in a timely manner
- Check with US Importer for specific documentation requirements for US Customs

Deloitte.



HIGHER RISK DEVICES:
Post-Emergency Use Authorization

What is normally required to commercially sell a Class II medical device in the US (e.g. Surgical Face Mask, N95 Respirator)?

- Submit a 510(k) to the US FDA for review and clearance ($11,594 FY20)
- Operate under a Quality Management System (QMS) that complies with the requirements of 21 CFR 820 and associated regulations
- Have a process for complying with Medical Device Reporting requirements under 21 CFR 803
- Have a process for complying with the requirements of 21 CFR 806 Reports of Corrective Actions and Removals (Recalls)
- Meet Unique Device Identifier (UDI) requirements
- Establishment Register and Device List ($5,236 in FY20)
- Obtain a US Agent
- Receive Clearance to Market letter from FDA for the device.

What is a 510(k)?

- A 510(k), also known as a Pre-Market Notification, is a technical document that is required to be submitted to FDA for review prior to the commercial distribution of moderate risk (mostly Class II) devices.
- The sponsor of a 510(k) must receive a Clearance to Market Letter from FDA before the product can be commercially distributed in the US.
- A 510(k) follows a standard format that includes several elements including:
  - Device Description
  - Testing results against relevant standards
  - Substantial Equivalence comparison to a predicate device
  - Indications for Use
  - Labeling

What is 21 CFR 820?

- 21 CFR 820 describes the requirements for a written quality system that covers the entire product lifecycle and that ensures the quality and performance of the device for its intended use and its useful life.
- Elements include:
  - Design Controls
  - Management Responsibility
  - Change Management
  - Corrective and Preventive Actions (CAPA)
  - Control of Non-Conforming Product (NCP)
  - Labeling and Package controls
  - Storage and Distribution controls

What is Medical Device Reporting (MDR)?

MDR is a requirement to report issues relates to patient safety (adverse events) and product quality of which a company becomes aware.

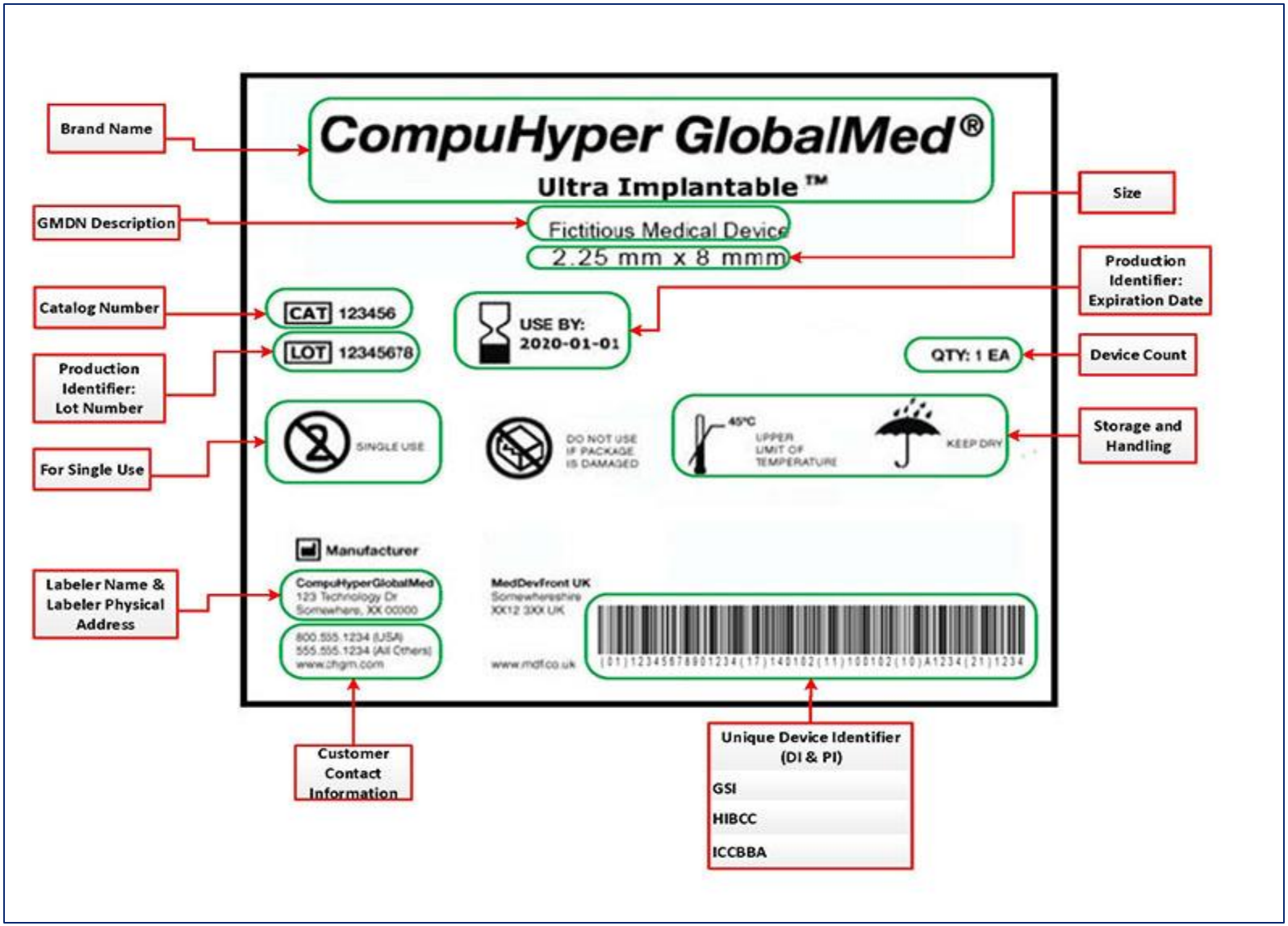
- MDR is mandatory
- There are time requirements – typically 30 days, but can be as short as 5 days, if requested by FDA
- Form FDA 3500A is used or submitted electronically through eMDR
- Requires investigation and follow-up
- Reportable events can come in from any source – complaints, distributors, etc.

What is Unique Device Identification (UDI) system?

"The FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use. MDR is mandatory."

- The system is still being implemented, but UDI is required for Class II medical devices.
- UDI is a code that enables FDA to determine what product went to which customer.
- Consists of a device identifier and a product identifier and may go down to a serial number per item
- For bulk packed devices the UDI may be part of the bulk package label

UDI example from FDA website



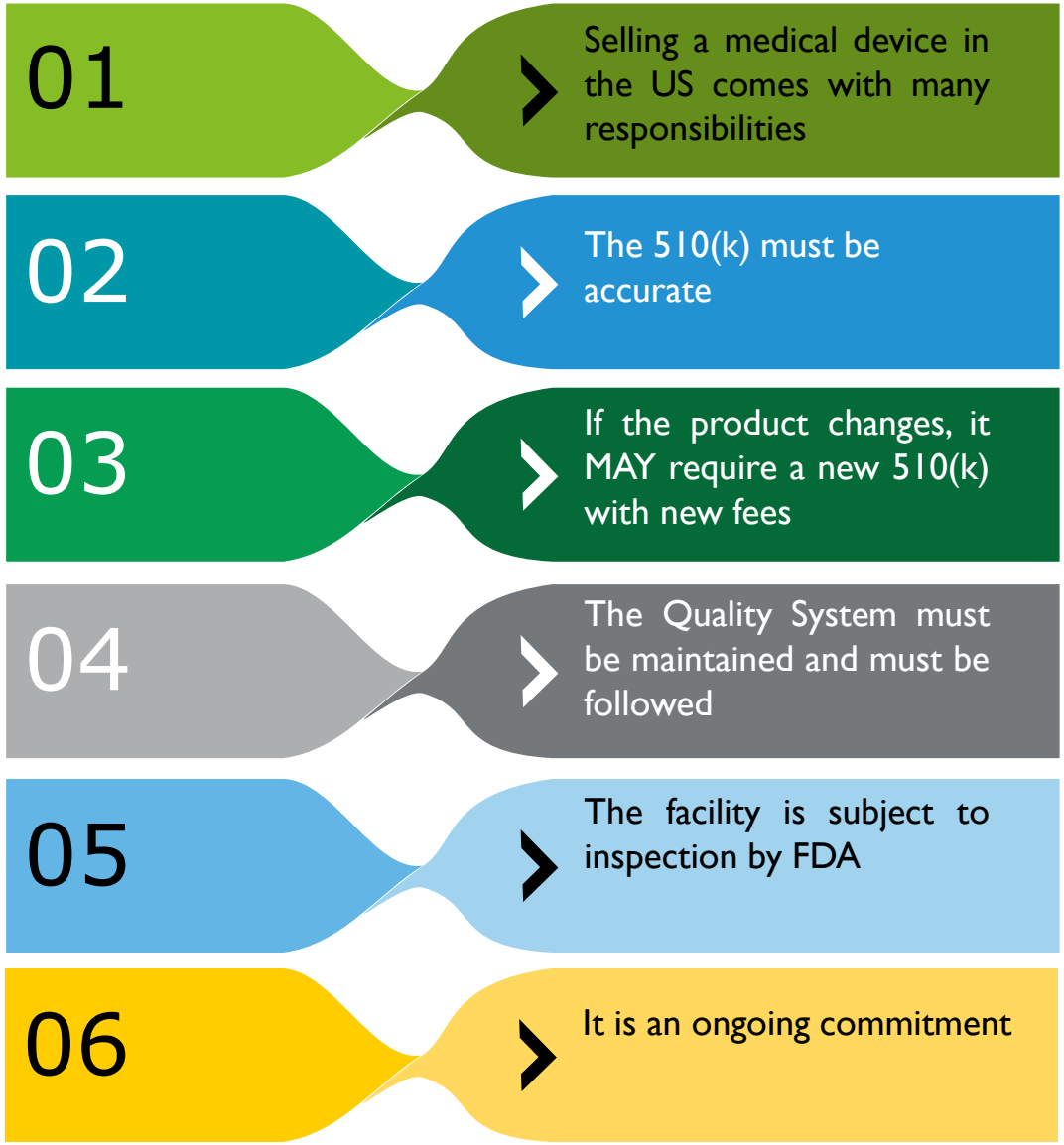
Establishment Registration , Device Listing, US Agent

- All facilities must be registered with FDA and renewed every year.
- If a company has more than one manufacturing and/or distribution facility, then each must be registered.
- Registration is done electronically
- The fee is paid every year
- Devices produced at the facility are listed in the database
- Every registered facility is subject to inspection by FDA
- US Agent – an individual with a physical address in the US, who serves as point of contact for a foreign manufacturer
- Can be anyone – often is the Importer
- Is a business relationship between the company and the agent, not FDA

Recommended process

- Identify product code and any relevant standards
- Conduct all necessary testing
- Prepare and submit 510(k)
- Develop Quality System in compliance with 21 CFR 820 / ISO 13485
- Develop other required processes, e.g. MDR, Recall, UDI
- Train personnel to all procedures as needed
- Respond to FDA questions around 510(k)
- Receive Clearance to Market Letter from FDA
- Establishment Register and Device List
- Retain US Agent (if not already retained from EUA period)
- Commercially ship product to US

Things to Consider



Questions?

Partnership for Accelerating Results in Trade, National Expenditure and Revenue (PARTNER) Activity