Importation of FDA Regulated Medical Devices:
Required Information and COVID

US Food and Drug Administration

Office of Enforcement and Import Operations

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Agenda

Importing Medical Devices	COVID and Medical Devices	Information and Resources
• What do filers transmit to FDA for medical device imports • What information should manufacturers and Importers provide	• FY 2021 • Enforcement Policies • Emergency Use Authorizations (EUAs) • Fraudulent Devices • Misleading FDA Registration Certificates • FDA Logo Policy	• Resources • Summary • FDA Points of Contact for Imports • Questions

Responsibility

FDA

- **FDA**
  - The Center for Devices and Radiological Health (CDRH) assures safe, effective, and high-quality medical devices and safe radiation-emitting products.
  - The Office of Enforcement and Import Operations (OEIO) manages ORA's field import operations, including investigational and compliance activities, and serves as the agency focal point for headquarters/field relationships on all import programs, operations, and problems.

- **Domestic Manufacturers**
  - Must meet FDA's regulatory requirements

- **Foreign Manufacturers**
  - Must meet FDA's regulatory requirements in order to import into the U.S.
  - Must designate a United States agent

- **Importers of Record**
  - Ensure compliance with all FDA laws and regulations
  - Ensure accurate information is provided to the filer

- **Brokers/Filers**
  - Ensure all FDA required information is supplied to FDA

Know the Product Being Imported

- *Component* means any **raw material, substance, piece, part, software, firmware, labeling, or assembly** which is intended to be included as part of the finished, packaged, and labeled device. (21 CFR 820.3(c))

- *Finished device* means any device or accessory to any device that is **suitable for use or capable of functioning**, whether or not it is packaged, labeled, or sterilized. (21 CFR 820.3 (I))

Combination Products

Therapeutic and diagnostic products that combine drugs, devices, and/or biological products.

These devices often must meet dual regulatory requirements

For more information: [Combination Products](#)

Information Needed for Submission
Program & Processing Codes

Program Code for medical device commodities is **<u>DEV</u>**.

The **Processing Code** will be determined by the commodity sub-type:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Medical Devices	DEV	Radiation Emitting Devices	RED
FDA	Medical Devices	DEV	Non-Radiation Emitting Devices	NED

Information Needed for Submission
Product Code Overview

Structure of the FDA Product Code					
Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or "-")	Process Identification Code – PIC (A or "-")	Product (AN)
Legend: N – Numeric; A – Alphabetic; AN - Alphanumeric					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.

- Use a valid FDA Product Code per the FDA Product Code Builder.

Information Needed for Submission
Product Descriptions, Packaging and Condition

- Data requirements depend on whether the product is:
  - Radiation Emitting Device
  - Non-Radiation Emitting Device

Data Requirement	Radiation Emitting Devices	Non-radiation Emitting Devices
Commodity Characteristic Description	Mandatory	Mandatory
Quantity and Packaging* (*If entered, the rules from the SG must be followed)	Mandatory if the product requires a 2877	Optional but encouraged
PGA Line Value	Optional but highly encouraged	Optional but highly encouraged

See the FDA Supplemental Guide for ACE for valid units of measure for medical device packaging containers.

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Information Needed for Submission
Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
081.001	- Standard import of device, accessories, or components regulated as a finished device - Import of refurbished device - Import of a reprocessed device	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
081.004	Foreign manufactured device that is Part of a medical device convenience kit	Mandatory: KIT, DEV, DFE, LST Conditional: PM#, LWC; IRC Optional: DI
081.005	Device constituent part for drug-device combination product	Mandatory: DEV, DFE, LST Conditional: DA, IND
081.007	Component for further manufacturing into a finished medical device	Mandatory: CPT Optional: LST, PM#

Additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

Information Needed for Submission
Intended Use Codes and Affirmations of Compliance

Intended Use Codes	Import Scenario	Affirmations of Compliance
170.000	Repair of medical device and re-exportation	Mandatory: IFE Conditional: DFE, LST, IRC, LWC, PM#, DDM Optional: DI
180.015	Import of a medical device for clinical investigational use	Mandatory: IDE
940.000	Compassionate Use/Emergency device	940.000
081.006	Import under enforcement discretions provisions per final guidance.	081.006
970.000	Import for Export: • Import of a medical device for further processing and re-exportation • Importation of a medical device or accessory for further manufacturing into an export-only medical device	Mandatory: DEV, DFE, IFE, LST
970.001	Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	Mandatory: IFE, CPT, DDM, LST

Information Needed for Submission
Entities

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and Email
Manufacturer (MF)	Mandatory	Mandatory	N/A
Shipper (DEQ)	Mandatory	Mandatory	N/A
FDA Importer (FD1)	Mandatory	Mandatory	Mandatory
Device Initial Importer (DII)	Mandatory	Mandatory	N/A
Delivered to Party (DP)	Mandatory	Mandatory	N/A
Filer's/Broker's Point of Contact (PK)	Optional but encouraged	Optional but encouraged	Optional but encouraged

- FEI number is preferred and DUNS number is encouraged when FEI number is unknown.

Summary

- Know the product being imported and associated requirements

- Provide correct and accurate information

- Obtain all necessary information prior to importation

NOTE: FDA will not be able to process an entry without complete and accurate information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.
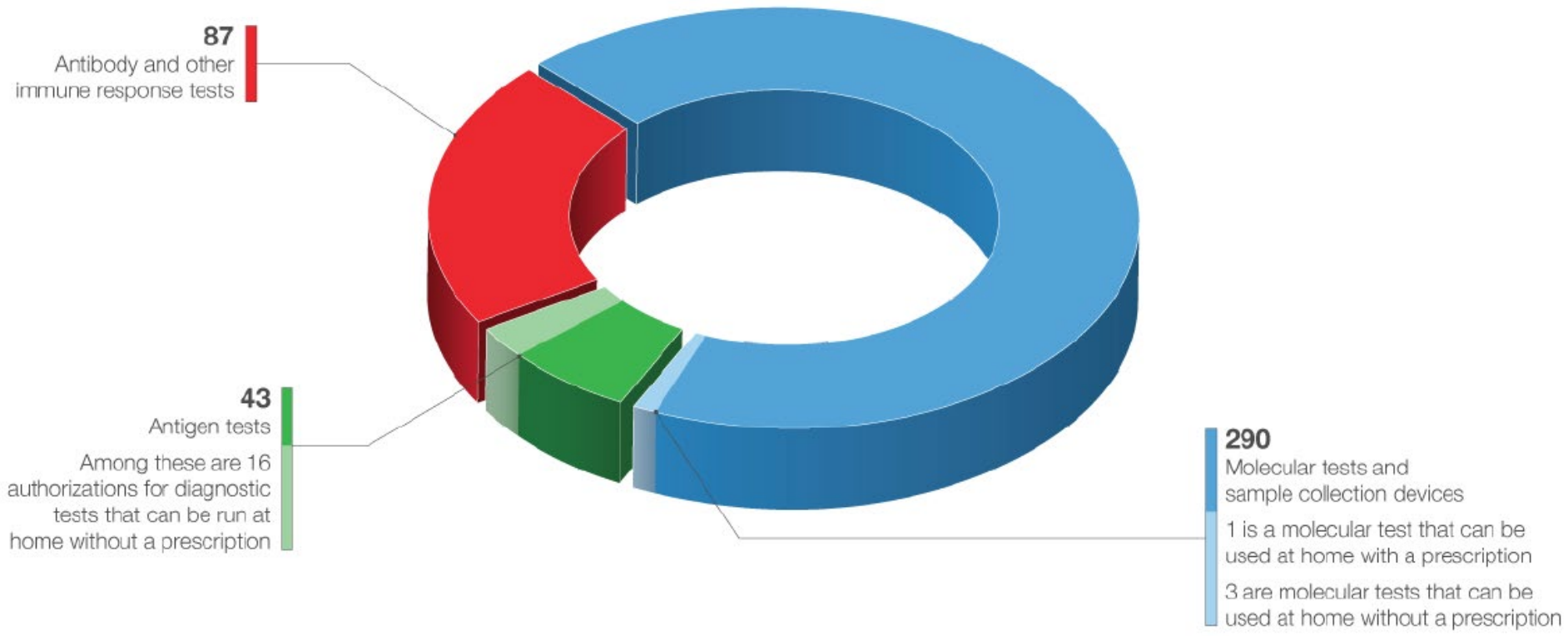
Importing Medical Devices

COVID-19

SARS-CoV-2 Testing

FDA has authorized EUAs for more than 400 tests and sample collection devices for SARS-CoV-2

As of December 31, 2021

87
Antibody and other immune response tests

43
Antigen tests

Among these are 16 authorizations for diagnostic tests that can be run at home without a prescription

290
Molecular tests and sample collection devices

1 is a molecular test that can be used at home with a prescription

3 are molecular tests that can be used at home without a prescription

[FDA 2021 Year in Review](#)

Enforcement Policies

FDA

- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) | FDA](#)
  - November 2021 is the most current revision

- [Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)](#)
  - September 2021 is the most current revision

[Search for FDA Guidance Documents](#)

Emergency Use Authorizations (EUAs)

FDA

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.

Products imported under an EUA are transmitted under IUC 940.000 Compassionate Use/Emergency Device

Emergency Use Authorization

Coronavirus Disease-2019 Tests

FDA issued [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) | FDA](#) to provide FDA's enforcement policies regarding certain novel COVID-19 tests

- The FDA expects COVID-19 tests to have been issued an EUA prior to the tests being offered for distribution

Emergency Use Authorization (EUA) of Covid-19 Test Kits

FDA

- There are several types of SARS-CoV-2 and COVID-19 related In Vitro Diagnostic (IVD) Tests:
  - Diagnostic Tests
  - Serology/Antibody and Other Adaptive Immune Response Tests:
  - Tests for Management of COVID-19 Patients
- [In Vitro Diagnostics EUAs | FDA](#) lists all EUAs that currently exist for IVDs
- As of November 15, 2021, FDA has authorized more than 420 tests for COVID-19, including more than 300 diagnostic and 90 serology tests
- Templates for EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA request
- Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov.

Transition Plans

FDA

Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency; Draft Guidance

This is a draft guidance. This document was issued to collect comments through a federal register notice. The comment period closed in March and FDA is reviewing those comments and no final guidance has been published.

Fraudulent COVID-19 Products

FDA

The FDA is actively monitoring for any firms marketing products with fraudulent COVID-19 prevention and treatment claims. The FDA is exercising its authority to protect consumers from firms selling unapproved products and making false or misleading claims, including, by pursuing warning letters, seizures, injunctions or criminal prosecutions against products and firms or individuals that violate the law.

[Fraudulent Coronavirus Disease 2019 (COVID-19) Products | FDA](#)

Counterfeit COVID-19 Tests

- [Counterfeit At-Home OTC COVID-19 Diagnostic Tests | FDA](#)
- The FDA is aware of counterfeit versions of FDA-authorized at-home over-the-counter COVID-19 diagnostic tests being distributed or used in the United States
- At this time, the FDA has identified the following counterfeit at-home OTC COVID-19 diagnostic tests:
  - Flowflex COVID-19 Antigen Home Tests
  - iHealth COVID-19 Antigen Home Tests
- The Agency issued the following safety communications : [Do Not Use Certain ACON Flowflex COVID-19 Tests: FDASafety Communication | FDA](#)
- A list of [authorized at-home OTC COVID-19 diagnostic tests](#) can be found at this link
- For more information about each test, including the Letter of Authorization and authorized labeling, see [In Vitro Diagnostics EUAs: Tables of IVD EUAs](#).
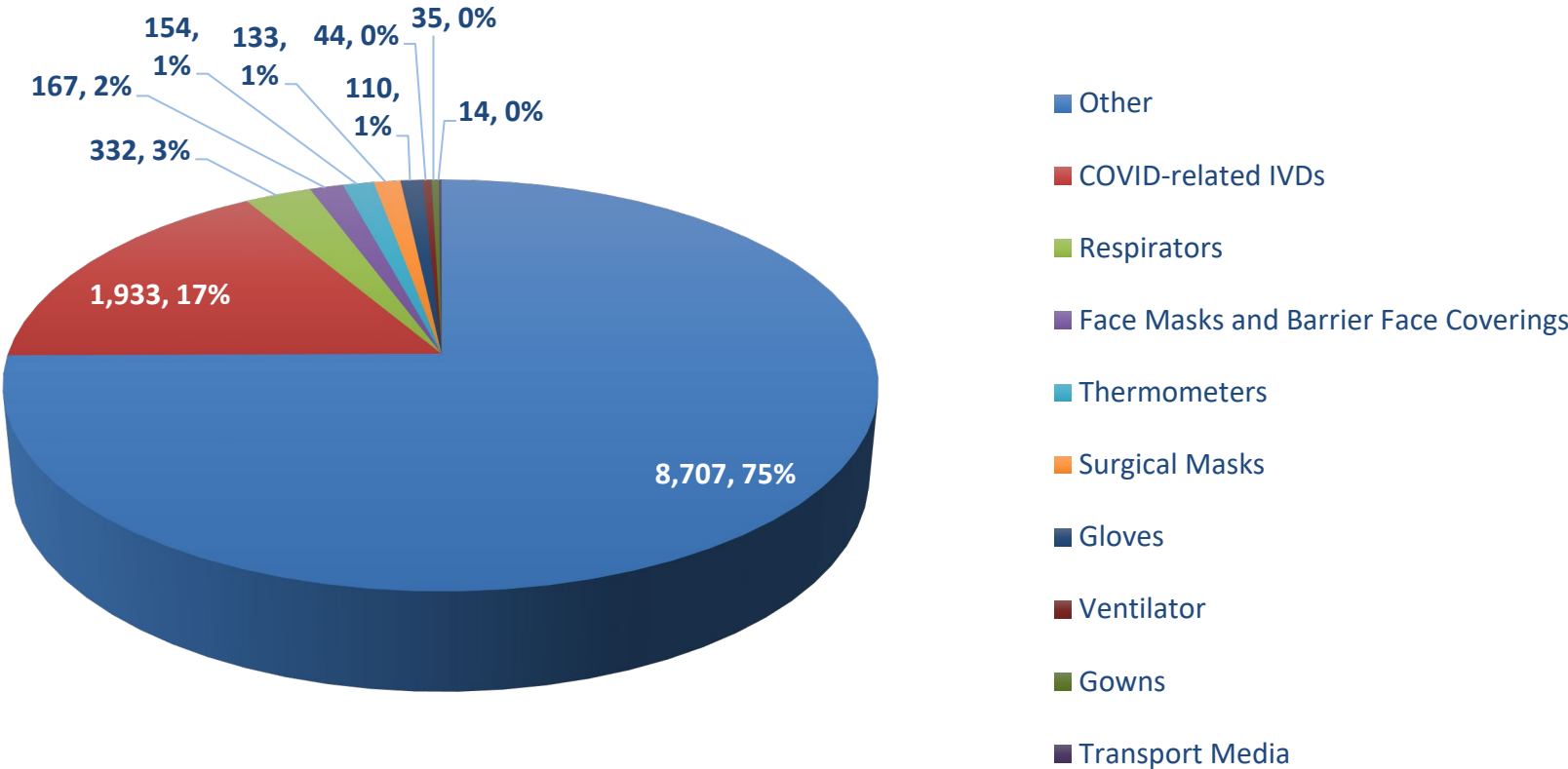
Quality Concerns

The FDA has become aware that gowns, including surgical gowns, purchased from Laws of Motion PPE may not provide protection, including fluid barrier protection, at the level for which the gowns are labeled.

[Stop Using Gowns, including Surgical Gowns, from Laws of Motion PPE - Letter to Health Care Providers | FDA](#)

Medical Device Refusals By Product Between 3/1/2020 and 5/31/2022

FDA

Legend:
- Other — 8,707, 75%
- COVID-related IVDs — 1,933, 17%
- Respirators — 332, 3%
- Face Masks and Barrier Face Coverings — 167, 2%
- Thermometers — 154, 1%
- Surgical Masks — 133, 1%
- Gloves — 110, 1%
- Ventilator — 44, 0%
- Gowns — 35, 0%
- Transport Media — 14, 0%

Misleading
"FDA Registration Certificates"

FDA's Logo Policy

The FDA logo is for official use of the U.S food and Drug Administration

- The FDA logo cannot be used by the private sector, including grantees, vendors and contractors.

A Warning Letter has been issued for unauthorized use of the FDA logo displayed alongside images of and information about the KN95 Mask:

- [Databazaar Warning Letter](#)

[FDA Logo Policy](#)

Importing Medical Devices

INFORMATION AND RESOURCES

COVID-19 Import Resources

[Importing Medical Devices During the COVID-19 Pandemic](#)

The FDA has taken action to help expand availability of medical devices that may be of use during the COVID-19 pandemic. Such medical devices generally fall into one of the following categories:

- Devices for which the FDA has issued a device-specific enforcement policy in [COVID-19-Related Guidance Documents](#). When imported, these devices should be declared as FDA-regulated with modified entry information specific to the enforcement policy.

- Devices that the FDA has authorized for emergency use. When imported, these devices should be declared as FDA-regulated with modified entry information per the EUA.

COVID-19 Import Resources

[Importing COVID-19 Supplies | FDA](#)

Shipment of COVID-19 supplies held-up at a port-of-entry?
- Contact the FDA office covering your port of entry.
    - [FDA Import Offices and Ports of Entry page](#)

General question regarding importing COVID-19 Supplies?
- Contact [COVID19 FDA IMPORT INQUIRIES](#)

To **ensure timely assistance** with an urgent need of COVID-19 supplies during the COVID-19 pandemic, please have the necessary information available, such as the:
- entry number (which you can get from your entry filer),
- port of entry, and
- other shipment details.

Resources Available

- For more information about medical devices, visit http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm

- For examples of accessories to medical devices, visit https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.pdf

- Device Advice, visit https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

- CDRH Learn, visit https://www.fda.gov/Training/CDRHLearn/default.htm

- Device Registration Database, visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

- Premarket Approval Database , visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

- Product Classification Database, visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

- Who Must Register and List, visit https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

Resources Available

- FDA ACE Affirmations of Compliance and Affirmations of Compliance Quick Reference at

  http://www.fda.gov/forindustry/importprogram/entryprocess/entrysubmissionprocess/ucm461234.htm

- FDA ACE/ITDS Webpage (including FDA Supplemental Guide) at https://www.fda.gov/industry/import-systems/automated-commercial-environmentinternational-trade-data-system-aceitds

- FDA DUNS Portal at https://fda.dnb.com/FDAUI/login.aspx and FDA Guide at https://www.fda.gov/media/95828/download

- Product Code Builder Tool and Tutorial at https://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm

- For more information about FDA's Import Program, visit http://www.fda.gov/forindustry/importprogram/default.htm

- For information about ACE Quantity Data Instructions, visit https://www.fda.gov/downloads/ForIndustry/ImportProgram/EntryProcess/ImportSystems/UCM487256.pdf

- FEI Search Portal: https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login

FDA Points of Contact for Imports

FDA Unit	Contact Information	Areas of Focus
CDRH Imports and Registration & Listing Team	cdrhimport@fda.hhs.gov	For questions regarding the regulatory requirements for the medical device being offered for import
FDA Imports Inquiry	FDAImportsInquiry@fda.hhs.gov 301-796-0356	General questions regarding FDA import operations and policy, including product classification (program, processing, product and HTS codes) and declaration
Import Offices and Ports of Entry	Import Offices and Ports of Entry	First-line support for product coding and entry-specific questions, including working through the FDA entry admissibility process, once the entry is successfully transmitted to FDA and accepted
ACE Support Center	ACE_Support@fda.hhs.gov Toll Free: 877-345-1101 Local/International: 571-620-7320	Technical issues related to the FDA supplemental guide, required data elements, and general ACE submission questions, including entry submissions rejected by FDA.

FDA Points of Contact for COVID

FDA

FDA Unit	Contact Information	Areas of Focus
CDRH Division of Microbiology Devices	CDRH-EUA-Templates@fda.hhs.gov (301) 348-1778	Inquiries about completing the EUA template, Pre-EUA/EUA submission to FDA, or questions about the use of an alternative specimen type.
CDRH	CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov	Inquiries about completing the EUA template, Pre-EUA/EUA submission to FDA.
FDA Imports COVID Inquiries	Covid19fdaimportinquiries@fda.hhs.gov	For assistance with import procedures regarding respirators, face masks, test kits, or other medical devices during the COVID-19 public health emergency.
CDRH	Contact the FDA About a Medical Device Supply Chain Issue Toll Free: 1-800-638-2041 Local or International: (301) 796-7100	To contact CDRH about any temporary or permanent supply disruptions, including notifications under Section 506J, of a medical device or radiation-emitting product.

FDA Points of Contact for Registration and Listing

FDA

FDA Unit	Contact Information	Areas of Focus
CDRH Registration and Listing Helpdesk	reglist@cdrh.fda.gov	For general registration and listing questions or for firms who need help with registration and listing
CDRH Registration and Listing staff	device.reg@fda.hhs.gov	For questions about a firm's registration and listing requirements

FDA

Questions

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