CSMS #42448725 - Information for Filing Personal Protective Equipment and Medical Devices During COVID-19

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The U.S. Food and Drug Administration is providing an update to CSMS messages 42124872 and 42168200 for instructions to the import community regarding the submission of entry information for personal protective equipment and certain other devices. Following the instructions below will help facilitate the import process for all; especially for products related to the Coronavirus Disease-2019 (COVID-19) public health emergency. It is in the best interest of the U.S. to facilitate and expedite the importation of products into the U.S. market that address immediate, urgent public health needs.

Because this a very fluid situation and FDA policy for these products are updated regularly, for the most up to date information on entry submission visit the FDA website: Information for Filing Personal Protective Equipment and Medical Devices During COVID-19.

Non-FDA-regulated general purpose personal protective equipment (masks, respirators, gloves, etc.)

Personal protective equipment for general purpose or industrial use (that is, products that are not intended for use to prevent disease or illness) is not regulated by FDA.

For these types of products, entry information should not be transmitted to FDA. At the time of entry for these products, Importers should transmit entry information to US Customs and Border Protection (CBP) using an appropriate HTS code with no FD Flag; or using an appropriate HTS code with an FD1 flag and do a 'disclaim' for FDA.

Products authorized for emergency use pursuant to an Emergency Use Authorization (EUA)

When importing such products, entry information should be submitted to FDA; however reduced FDA information is required for review.

At the time of entry, Importers should transmit an Intended Use Code of 940.000: Compassionate Use/Emergency Use Device, and an appropriate FDA product code. Under this Intended Use Code, the Affirmations of Compliance for medical devices (such as the Registration, Listing, and Premarket numbers) are optional in ACE.

Below is a list of products and certain product codes authorized by an EUA. A complete list of product codes may be found in corresponding enforcement policy guidance documents identified below.

- Non-NIOSH-Approved Respirators: 80QKU
- NIOSH-Approved Respirators
- Face Masks (Non-Surgical)
- Diagnostic Tests Kits
- Ventilators
- Face Shields
- Respirator Decontamination Systems
- Extracorporeal Blood Purification Devices
- Infusion Pumps
- Ventilators
- Diaphragmatic Pacing Simulator Systems

A full list of Emergency Use Authorizations currently in place for the COVID-19 emergency is also available on the FDA's website. Please check this site regularly for current information on products authorized by an EUA. Future updates to this message will only identify new EUAs in this section. The full list will be provided on the FDA website: Information for Filing Personal Protective Equipment and Medical Devices During COVID-19.

Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance.

When importing such devices entry information should be submitted to FDA

When importing such devices, entry information should be submitted to FDA.

At the time of entry, Importers should transmit Intended Use Code 081.006: Enforcement discretion per final guidance, and an appropriate FDA product code. Under this Intended Use Code, the Affirmations of Compliance for medical devices (such as the Registration, Listing, and Premarket numbers) are optional in ACE.

Below is a listing of guidance documents that have been issued for specific products related to COVID-19, which reference applicable product codes and policy for those products:

- Telethermographic Systems
- Remote Ophthalmic Assessment and Monitoring Devices
- Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices
- Infusion Pumps and Accessories
- Digital Health Devices for Treating Psychiatric Disorders
- Clinical Electronic Thermometers
- Gowns, Other Apparel, and Gloves
- Sterilizers, Disinfectant Devices and Air Purifiers
- Face Masks and Respirators
- Non-Invasive Remote Monitoring Devices
- Ventilators and Accessories and Other Respiratory Devices
- Diagnostic Tests

A full list of all guidance documents related to COVID-19 is also available on FDA's website. For guidance applicable to medical devices, you may filter by the medical device product area and display all entries. Please check this site, as well as Information for Filing Personal Protective Equipment and Medical Devices During COVID-19, regularly for current information on these and other product areas.

All questions regarding these instructions, product code assistance for these products, or to resolve entry issues can be submitted to FDA at: COVID19FDAIMPORTINQUIRIES@fda.hhs.gov or 301-796-0356.

Step-by-Step instructions on how to register and list can be found on our website at: https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing.

For additional assistance with completing initial registration, firms should contact the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

For assistance with paying the annual registration user fee, firms can reach out to the User Fee Helpdesk at userfees@fda.gov.

For further information regarding entry submission requirements in the Automated Commercial Environment (ACE) system, see the FDA Supplemental Guide for ACE at

https://www.cbp.gov/sites/default/files/assets/documents/2020-Mar/FDA%20Supplemental%20Guide%20Release%202.5.1%202018%200410.pdf

As usual, FDA may request additional information on a case-by-case basis for making its final admissibility decision.