O R A C L E

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NEWSLETTER FROM DELPHI CONSULTING GROUP (DCG)

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The ORACLE is a free newsletter of recent medical device regulatory & computer information that is of interest to designers, and device manufactures.

Delphi Consulting Group (DCG), provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs

FY 2021 MDUFA User Fees

Just a reminder, the FDA User Fees for FY 2021 are now in effect. The Annual Establishment Registration Fee: $5,546 is due now to December 2020. No breaks for small business.

Importing Medical Devices during the COVID-19 Pandemic

[SIC DCG has received a large number of requests on this subject].

The Food and Drug Administration (FDA) continues critical work to protect public health, including the review of shipments of medical devices offered for import during the COVID-19 pandemic. This page provides information on importing certain medical devices during the COVID-19 pandemic. It describes procedures for importing devices that have been issued Emergency Use Authorizations (EUA) and for devices for which an enforcement discretion policy has been published in guidance. It does not address products that are intended only for use in industrial or manufacturing settings, or construction or home improvement (i.e., not intended for a medical purpose), which are appropriate to disclaim on entry.

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 guidance. When imported, these devices should be declared as FDA-regulated with modified entry requirements specific to the enforcement policy. These guidance documents describe circumstances during which the FDA does not intend to object to certain device modifications, or the distribution and use of some types of devices, without compliance with certain regulatory requirements as explained in each specific policy. Please see COVID-19-Related Guidance Documents web page.

• Devices for which the FDA has issued an emergency use authorization (EUA). When imported, these devices should be declared as FDA-regulated with modified entry requirements as allowed by the EUA authorizing the device for emergency use

Importing Respirators, Face Masks, and PPE

Q: How do I import NIOSH-approved respirators?

A: For National Institute for Occupational Safety and Health (NIOSH)-approved N95s, see the EUA for NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency. Respirators are authorized for emergency use pursuant to the EUA if they appear on the following NIOSH Certified Equipment Lists (CEL): NIOSH CEL for non-powered air purifying respirators with particulate protection or NIOSH CEL for PAPRs with particulate protection or are NIOSH-approved but have since passed the manufacturers' recommended shelf-life. Please see, Importing Medical Devices and Radiation-Emitting Electronic Products into the U.S. for detailed instructions for importing medical devices.

Q: Where can I find information about importing non-NIOSH approved respirators?

A: See the applicable EUA below.

• Non-NIOSH-approved Filtering Facepiece

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Respirators (FFRs) made in China authorized for emergency use are listed on Appendix A of the FDA's EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China.

• Non-NIOSH-approved FFRs made in other countries authorized for emergency use are listed on Exhibit 1 of the FDA Emergency Use Authorization (EUA) for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators.

Q: Am I required to register and list non-NIOSH approved respirators that are authorized under an EUA?

A: You must register and list if required by your device's EUA letter of authorization.

Q: Which FDA product code do I use to import non-NIOSH-approved respirators, specifically KN95s from China, if they are authorized by EUA?

A: FDA Product code 80Q -- KU may be used for non-NIOSH-Approved Disposable FFRs. This includes all non-NIOSH-approved FFRs authorized under an EUA.

Q: How do I import respirators that are not authorized under an EUA?

A: The FDA does not allow the importation of a respirator unless it is authorized by an EUA or is FDA-cleared or NIOSH-approved. See 21 CFR 880.6260.

Q: How do I import respirators for use as face masks?

A: The FDA's EUA for face masks describes the conditions under which face masks are authorized for emergency use. Respirators that do not satisfy the requirements of one of the respirator EUAs but that the requirements in the EUA for face masks (including labeling reqirements) may be authorized under that EUA and imported.

Q: Can I import general purpose face masks from China?

A: Yes. Face masks for general purpose -- that is, products that are not intended for a medical purpose such as preventing transmission of infection through respiratory secretions, and that are labeled only for general purposes such as industrial use -- may be imported. For face masks not intended for a medical purpose, entry information is not transmitted to the FDA; however, importers/filers should continue to transmit entry information to U.S. Customs and Border Protection (CBP).

Q: How can I import personal protective equipment (PPE), other than masks or respirators, for use during the COVID-19 pandemic? Do I need to register and list to import my PPE?

A: During the COVID-19 pandemic, the FDA is working to help facilitate the importation of critically needed FDA-regulated Personal Protective Equipment (PPE) into the United States. Please see the applicable PPE EUAs, listed on the Emergency Use Authorizations for Medical Devices webpage, for example, Face Shields. Additionally, FDA has issued several enforcement policy guidances, listed on the COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders webpage, for example, Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency.

• Medical Devices Authorized For Emergency Use

For devices that have been issued an EUA, it is appropriate to transmit the Intended Use Code (IUC) 940.000 (Compassionate Use/Emergency Use Device) when filing an entry. During the COVID-19 Public Health Emergency, registration, listing and premarket approval or clearance file numbers may be optionally transmitted at the time of entry. You must register and list if required by your device's EUA letter of authorization.

• Medical Devices within the Scope of an Enforcement Policy Guidance

If your device is within the scope of an enforcement policy guidance and the enforcement policy applies, it is appropriate to transmit the Intended Use Code (IUC) 081.006 (Enforcement Discretion per Final Guidance) when filing an entry. During the COVID-19 Public Health Emergency, registration, listing and premarket approval or clearance file numbers may be optionally transmitted at the time of entry. These guidance documents describe circumstances during which the FDA does not intend to object to certain device modifications, or the distribution and use of some types of devices, without compliance with certain regulatory requirements as explained in each specific policy. For some of these policies, these regulatory requirements include registration and listing.

Q: I saw online that I can buy N95 respirators that are "FDA Certified" and include the FDA logo on the product box. Does the FDA certify N95 respirators?

A: No. The FDA does not certify products and the FDA logo is for the official use of the FDA and not for use on private sector materials. The FDA does not issue registration certificates to

medical device facilities nor does the FDA certify information for facilities that have registered their establishments and listed their medical products. When a facility registers and lists its devices, the resulting entry in FDA's registration and listing database does not denote approval, clearance or authorization of that facility or its medical devices. See also, policy on use of the FDA logo.

Purchasers may verify the clearance or approval status of medical devices, unless exempt from premarket review, by searching the Premarket Notifications (510(k)s), De Novo, or Premarket Approvals (PMA) database, using the device trade name as the search criterion. You may also verify registration and listing status for medical devices, including those exempt from premarket review, by searching the Establishment Registration & Device Listing database, using the establishment name as the search criterion. Purchasers may also verify whether specific products have been authorized for emergency use during the COVID-19 emergency by referencing the Emergency Use Authorizations page.

Donating Medical Devices

Q: I want to donate masks or other equipment for the emergency. How do I import such donations?

A: If you are interested in donating masks or other equipment, please see FEMA's COVID-19 Offer of Medical Supplies or Equipment donation webform.

Importing Other Medical Devices

Q: How do I import into the U.S. sterilizers, disinfectant devices, and air purifiers that are within the scope of FDA's enforcement policy guidance? Am I required to register and list?

A: The FDA issued an Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease (COVID-19) Public Health Emergency that describes the policy for these devices. If your device is within the scope of the guidance and the enforcement policy applies, it is appropriate to transmit the Intended Use Code (IUC) 081.006 (Enforcement Discretion per Final Guidance) when filing an entry. Registration, listing, and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. The enforcement policy describes the circumstances during which the FDA does not intend to object to certain modifications to, or the distribution and use of, devices within the scope of the guidance without compliance with certain regulatory requirements, including registration and listing.

Q: How do I import ventilators that have been issued an Emergency Use Authorization (EUA)? Am I required to register and list?

A: The FDA issued an Emergency Use Authorization for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators, ventilator tubing connectors, and ventilator accessories. This EUA addresses devices that are not currently marketed in the United States as well as situations where a modification to an FDA-cleared ventilator that does not fall within the scope of the Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. We recommend that you also provide a copy of the signed EUA Letter of Authorization as part of your Import Entry documentation.

If your ventilator, ventilator tubing connector, or ventilator accessory is listed in Appendix B of the EUA it is appropriate to transmit the Intended Use Code (IUC) 940.000 (Compassionate Use/Emergency Use Device) when filing an entry. Registration, listing and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. You must register and list if required by your device's EUA letter of authorization.

Additionally, the FDA issued an Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. If your device is within the scope of the guidance and the enforcement policy applies, it is appropriate to transmit the Intended Use Code (IUC) 081.006 (Enforcement Discretion per Final Guidance) when filing an entry. Registration, listing and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. This policy does not address registration and listing requirements.

Q: How do I import thermometers that are within the scope of the Enforcement Policy for Clinical Electronic Thermometers? Am I required to register and list?

A: The FDA issued an Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public

Health Emergency. If your device is within the scope of the guidance and the enforcement policy applies, it is appropriate to transmit the Intended Use Code (IUC) Intended Use Code (IUC) 081.006 (Enforcement Discretion per Final Guidance), with the device product code when filing an entry. Registration, listing, and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. The enforcement policy describes the circumstances during which the FDA does not intend to object to the distribution and use of devices within the scope of the guidance without compliance with certain regulatory requirements, including registration and listing.

Q: How do I import ophthalmic devices that are within the scope of the Enforcement Policy for Remote Ophthalmic Assessment and Monitoring devices?

A: The FDA issued an Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices. If your device is within the scope of the guidance and the enforcement policy applies, it is appropriate to transmit the Intended Use Code (IUC) Intended Use Code (IUC) 081.006 (Enforcement Discretion per Final Guidance), with the device product code when filing an entry. Registration, listing, and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. This policy does not address registration and listing requirements.

Q: How do I import infusion pumps that are within the scope of the Enforcement Policy for Infusion Pumps and Accessories?

A: The FDA has issued an Enforcement Policy for Infusion Pumps and Accessories. If your product is within the scope of the guidance and the enforcement policy applies, it is appropriate to transmit the Intended Use Code (IUC) 081.006 (Enforcement Discretion per Final Guidance) with the relevant device product code. Registration, listing, and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. The enforcement policy describes the circumstances during which the FDA does not intend to object to the distribution and use of devices within the scope of the guidance without compliance with certain regulatory requirements, including registration and listing.

Manufacturers of devices not already cleared for use in the United States may request emergency use authorization as outlined in the guidance. For questions about the EUA process, contact CDRH-COVID19-InfusionPumps@fda.hhs.gov

Q: How do I import extracorporeal membrane oxygenation (ECMO) and cardiopulmonary bypass devices and accessories that have been issued an EUA or are within the scope of the Enforcement Policy for ECMO and Cardiopulmonary Bypass Devices?

A: For devices that have been issued an EUA, it is appropriate for importers to transmit the Intended Use Code (IUC) 940.000 (Compassionate Use/Emergency Use) when filing an entry. The EUA list can be found on the Emergency Use Authorizations for Medical Devices webpage. Registration, listing and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. You must register and list if required by your device's EUA letter of authorization. We recommend that you also provide a copy of the signed EUA Letter of Authorization as part of your Import Entry documentation.

The FDA has issued an Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. If your prduct is within the scope of the guidance and the enforcement policy applies, it is appropriate for importers to transmit the Intended Use Code (IUC) 081.006 (Enforcement Discretion per Final Guidance) and the FDA product code when filing an entry. Registration, listing and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. This policy does not address registration and listing requirements.

Q: How do I import tests for COVID-19? Am I required to register and list?

A: For devices that have been issued an EUA, it is appropriate for importers to transmit the Intended Use Code (IUC) 940.000 (Compassionate Use/Emergency Use Device) when filing an entry. We recommend that you also provide a copy of the signed EUA Letter of Authorization as part of your Import Entry documentation. Registration, listing, and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. You must register and list if required by your device's EUA letter of author-

ization.

FDA has issued a Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. If your product is within the scope of the guidance and one of the policies within the guidance applies, it is appropriate for importers to transmit Intended Use Code (IUC) 081.006 (Enforcement Discretion per Final Guidance) when filing an entry. Registration, listing, and premarket approval or clearance file numbers may be optionally transmitted at the time of entry when using this IUC. This policy does not address registration and listing requirements.

Checking Import Status and Contact for Import Questions

Q: How do I check the status of my imported devices?

A: If you are importing a product that's regulated by the FDA, then an FDA entry number will be assigned to determine the admissibility of the product. We recommend that you also provide a copy of the signed EUA Letter of Authorization as part of your Import Entry documentation.

You can also check the status of the shipment by using the Import Trade Auxiliary Communications System (ITACS) portal.

Q: Who do I contact if I have a question about importing a device?

A: For questions regarding the regulatory requirements for the medical device being offered for import, please contact the CDRH Imports and Registration & Listing Team at: cdrhimport@fda.hhs.gov.

For assistance with general import procedures regarding personal protective equipment, test kits, or other products related to the public health emergency, please contact: COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Inquiries related to a specific import entry are most appropriately routed to the FDA Import Division handling the entry.

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LibreOffice will run on Mac, PC and Linux in native mode or save files in doc/docx. It does a very good job of accepting Word files. Also of importance it can produce 'real' PDF copies of documents that do not contain restrictive code.

Considering how this year has gone maybe it is time to put up a Christmas tree or what is the correct symbol for you, and just call it a year.

Be safe, Wear a mask, be home, and be smart.