Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Charles Viviano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2680, Silver Spring, MD 20993–0002, 240–402–2975.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this draft guidance to propose select updates to the FDA guidance document ''Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' The existing guidance on devices used for the treatment of BPH remains in effect, in its current form, until this draft guidance is finalized. FDA intends to incorporate this draft guidance into one final guidance document after obtaining and considering public comment on these select updates. The sections of the existing BPH guidance that are not affected by this select update will not be substantively changed and will remain in effect.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1724 and the full title to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
807, subpart E	Premarket Notification	0910–0120
812	Investigational Device Exemption	0910–0078
814, subparts A through E	Premarket Approval Applications	0910–0231
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo Classification Process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15089 Filed 7–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance and reissuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA has issued, and in some cases reissued, the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance and reissuance, are listed in this document, and are available on FDA's website at the links indicated.

DATES: These Authorizations are applicable on their date of issuance.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. The Authorizations

Having concluded that the criteria for the issuance and, in some cases reissuance, of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, are available on the internet from the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued, in some cases reissued, from April 11, 2020, through May 15, 2020, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. FDA is

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

hereby announcing the following Authorizations for in vitro diagnostics: [3]

- Ortho-Clinical Diagnostics, Inc.'s VITROS Immunodiagnostic Products Anti-SARS–CoV–2 Total Reagent Pack, issued April 14, 2020;
- Chembio Diagnostic System, Inc.'s DPP COVID–19 IgM/IgG System, issued April 14, 2020;
- Mount Sinai Laboratory's COVID–19 [enzyme-linked immunosorbent assay] ELISA IgG Antibody Test, issued April 15, 2020;
- Maccura Biotechnology (USA) LLC's SARS–CoV–2 Fluorescent PCR Kit, issued April 15, 2020;
- GenoSensor, LLC's GS COVID–19 RT–PCR KIT, issued April 16, 2020;
- KorvaLabs Inc.'s Curative-Korva SARS–CoV–2 Assay, issued April 16, 2020;
- Fosun Pharma USA Inc.'s Fosun COVID–19 RT–PCR Detection Kit, issued April 17, 2020;
- OSANG Healthcare's GeneFinder COVID–19 Plus RealAmp Kit, issued April 18, 2020;
- Trax Management Services Inc.'s PhoenixDx 2019–CoV, issued April 20, 2020;
- Laboratory Corporation of America's COVID–19 RT–PCR Test, reissued April 20, 2020 (original issuance March 16, 2020);
- Seegene, Inc.'s Allplex 2019–nCoV Assay, issued April 21, 2020;
- altona Diagnostics GmbH's RealStar SARS–CoV–2 RT–PCR Kits U.S., issued April 22, 2020;
- SD Biosensor, Inc.'s STANDARD M nCoV Real-Time Detection Kit, issued April 23, 2020;
- Autobio Diagnostics Co. Ltd.'s Anti-SARS–CoV–2 Rapid Test, issued April 24, 2020;
- Ortho-Clinical Diagnostics, Inc.'s VITROS Immunodiagnostic Products Anti-SARS–CoV–2 IgG Reagent Pack, issued April 24, 2020;
- DiaSorin Inc.'s LIAISON SARS–CoV–2 S1/S2 IgG, issued April 24, 2020;
- Abbott Laboratories Inc.'s SARS–CoV–2 IgG assay, issued April 26, 2020;
- SEASUN BIOMATERIALS's U–TOP COVID–19 Detection Kit, issued April 27, 2020;
- Bio-Rad Laboratories, Inc's Platelia SARS–CoV–2 Total Ab assay, issued April 29, 2020;
- Rheonix, Inc.'s Rheonix COVID–19 MDx Assay, issued April 29, 2020;
- LabGenomics Co., Ltd.'s LabGun COVID–19 RT–PCR Kit, issued April 29, 2020;
- Wadsworth Center, New York State Department of Health's New York SARS–CoV Microsphere Immunoassay for Antibody Detection, issued April 30, 2020;
- BioFire Diagnostics, LLC's BioFire Respiratory Panel 2.1 (RP2.1), issued May 1, 2020;
- Bio-Rad Laboratories, Inc.'s Bio-Rad SARS–CoV–2 ddPCR Test, issued May 1, 2020;
- Roche Diagnostics's Elecsys Anti-SARS–CoV–2, issued May 2, 2020;
- Sansure BioTech Inc.'s Novel Coronavirus (2019–nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing), issued May 4, 2020;
- EUROIMUN US Inc.'s Anti-SARS–CoV–2 ELISA (IgG), issued May 4, 2020;
- Fast Track Diagnostics Luxembourg S.á.r.l's. (a Siemens Healthineers Company) FTD SARS–CoV–2, issued May 5, 2020;
- BioMérieux SA's SARS–COV–2 R–GENE, issued May 6, 2020;
- Sherlock BioSciences, Inc.'s Sherlock CRISPR SARS–CoV–2 Kit, issued May 6, 2020;
- OPTI Medical Systems, Inc.'s OPTI SARS–CoV–2 RT PCR Test, issued May 6, 2020;
- Zymo Research Corp.'s Quick SARS–Cov–2rRT–PCR Kit, issued May 7, 2020;
- Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics-Rutgers University's Rutgers Clinical Genomics Laboratory TaqPath SARS–CoV–2 Assay, reissued May 7, 2020 (original issuance April 10, 2020);
- Gnomegen LLC's Gnomegen COVID–19–RT–qPCR Detection Kit, issued May 8, 2020;
- Quidel Corporation's Sofia 2 SARS Antigen FIA, issued May 8, 2020;
- Abbott Molecular Inc.'s Alinity m SARS–CoV–2 assay, issued May 11, 2020;
- 1drop Inc.'s 1copy COVID–19 qPR Multi Kit, issued May 11, 2020;
- Applied DNA Sciences, Inc.'s Linea COVID–19 Assay Kit, issued May 13, 2020;
- GeneMatrix, Inc.'s NeoPlex COVID–19 Detection Kit, issued May 14, 2020;
- Hologic, Inc., Aptima SARS–CoV–2 assay, issued May 14, 2020;
- Assurance Scientific Laboratories' Assurance SARS–CoV–2 Panel, issued May 15, 2020;
- Fulgent Therapeutics, LLC's Fulgent COVID–19 by RT–PCR Test, issued May 15, 2020; and
- Certain SARS–CoV–2 Antibody Tests (lateral flow or ELISA tests) that are for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263a, to perform moderate or high complexity tests, issued on April 28, 2020 (a current list of tests included under this EUA is available at *https://www.fda.gov/media/137471/download*).

FDA is hereby announcing the following Authorizations for personal respiratory protective devices: [4]

- Certain Non-[National Institute of Industrial and Occupational Safety]NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China, reissued May 7, 2020, (original issuance April 3, 2020). A current list of respirators included under this EUA is available at *https://www.fda.gov/media/136663/download*).

FDA is hereby announcing the following Authorizations for other medical devices:

- B. Braun Medical, Inc.'s B. Braun Space and Outlook Pumps, issued April 11, 2020; [5]
- Advanced Sterilization Products, Inc.'s ASP STERRAD Sterilization Systems, issued April 11, 2020; [6]

[3] As set forth in the EUAs for these devices, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the devices may be effective in diagnosing COVID–19, and that the known and potential benefits of the devices, when used for diagnosing COVID–19, outweigh the known and potential risks of such devices; and (3) there is no adequate, approved, and available alternative to the emergency use of the devices.

[4] As set forth in the EUAs, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is either reasonable to believe that the authorized respirators may be effective in preventing healthcare personnel (HCP) exposure to pathogenic biological airborne particulates during Filtering Facepiece Respirator (FFR) shortages, and that the known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages during COVID–19, outweigh the known and potential risks of such products, and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[5] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the B. Braun Space and Outlook Pumps may be effective for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat COVID–19 patients of all ages and for the ground medical transport use of the Infusomat Space Volumetric Infusion Pump System, and that the known and potential benefits of the B. Braun Space and Outlook Pumps for these uses, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[6] As set forth in this EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to

Continued

- Certain Face Shields, reissued April 13, 2020 (original issuance April 9, 2020); [7]
- Synapse Biomedical, Inc.'s TransAeris Diaphragm Pacing System, issued April 13, 2020; [8]
- Stryker Instruments' STERIZONE VP4 Sterilizer, issued April 14, 2020; [9]
- Lungpacer Medical USA, Inc.'s Lungpacer DPTS, issued April 14, 2020 (see footnote 8);
- ExThera Medical Corporation's Seraph 100 Microbind Affinity Blood Filter, issued April 17, 2020; [10]
- Certain Face Masks, issued April 18, 2020, and reissued April 24, 2020; [11]
- Sterilucent, Inc.'s Sterilucent Sterilizer System, issued April 20, 2020; [12]
- Philips Medizin Systeme Boeblingen GmbH's IntelliVue Patient Monitors, issued April 21, 2020; [13]
- ALung Technologies, Inc.'s Hemolung RAS, issued April 22, 2020; [14]
- Baxter Healthcare Corp.'s oXiris Set device, issued April 23, 2020; [15]
- VitalConnect, Inc.'s VitalPatch, issued April 26, 2020; [16]
- Fresenius Medical Care's multiFiltrate PRO System and multiBic/multiPlus Solutions to provide continuous renal replacement therapy, issued May 1, 2020; [17]
- Liberate Medical, LLC's VentFree, issued May 1, 2020; [18]

FDA, it is reasonable to believe that the ASP STERRAD Sterilization Systems may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of N95 respirators during the COVID–19 pandemic by decontaminating, for a maximum of two decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS–CoV–2 or other pathogenic microorganisms, and that the known and potential benefits of the Sterilization Systems, when used to decontaminate compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic airborne particulates during N95 respirator shortages during the COVID–19 pandemic, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[7] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face shields may be effective at preventing HCP exposure to fluid biological airborne particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer, and that the known and potential benefits of face shields, when used to prevent HCP exposure to such particulates during face shield shortages during COVID–19 outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[8] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective for emergency use to treat patients by assisting in weaning patients off ventilators in healthcare settings during the COVID–19 pandemic, and that the known and potential benefits of the such product, for such use, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative.

[9] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the STERIZONE VP4 N95 Respirator Decontamination Cycle may be effective at preventing exposure to pathogenic airborne particulates by decontaminating, for a maximum of two decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS–CoV–2 or other pathogenic microorganisms, and that the known and potential benefits of this device, when used as described, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle for decontaminating compatible N95 respirators for single-user reuse by HCPs during FFR shortages during the COVID–19 pandemic.

[10] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Seraph 100 Microbind Affinity Blood Filter device may be effective in treating patients 18 years of age or older with confirmed COVID–19 admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure, and that the known and potential benefits of the Seraph 100 Microbind Affinity Blood Filter device, when used to treat such patients, outweigh the known and potential risks of the device; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[11] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face masks may be effective as source control to help prevent the spread of SARS–CoV–2 by infected individuals who may or may not have symptoms of COVID–19 during the COVID–19 pandemic, and that the known and potential benefits of face masks, when used in accordance with the scope of this authorization, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[12] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Sterilucent Sterilization System may be effective at decontaminating compatible N95 respirators for single-user reuse by HCPs to prevent exposure to pathogenic biological airborne particulates, and that the known and potential benefits of this device, when used as described, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[13] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the IntelliVue Patient Monitors may be effective in preventing COVID–19 exposure in healthcare providers, through use of remote patient monitoring, and that the known and potential benefits of such products, for such use, outweigh the known and potential risks of the IntelliVue Patient Monitors; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[14] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Hemolung RAS may be effective in treating lung failure when used as described in the Scope of Authorization, and that the known and potential benefits of the Hemolung RAS for treating these patients, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[15] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the oXiris Set device may be effective in treating patients 18 years of age or older with confirmed COVID–19 admitted to the ICU with confirmed or imminent respiratory failure in need of blood purification, including use in continuous renal replacement therapy, and that the known and potential benefits of the oXiris Set device, when used to treat such patients, outweigh the known and potential risks of the oXiris Set device; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[16] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in remotely monitoring and detecting QT interval changes of an ECG in patients who are undergoing treatment in a hospital setting for COVID–19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (*e.g.,* hydroxychloroquine or chloroquine, especially when used in combination with azithromycin), the known and potential benefits of product for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[17] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness and multiple organ failure, including acute kidney injury, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that your multiFiltrate PRO System and multiBic/multiPlus Solutions may be effective in delivering CRRT in an acute care environment, and that the known and potential benefits of the multiFiltrate PRO System and multiBic/multiPlus Solutions, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[18] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes

• Certain Protective Barrier Enclosures, issued May 1, 2020; [19]
• PhsiolGuard Corp. Ltd.'s PhysiolGuard ECG–QT Analysis System, issued May 5, 2020 (refer to footnote 15);
• Duke University Health System's Duke Decontamination System, issued May 7, 2020; [20]
• Comunale's Patient Isolation Transport Unit, issued May 8, 2020; [21]
• Ascom (US) Inc.'s teleCARE IP Nurse Call System, issued May 11, 2020; [22]
• Eko Devices, Inc.'s Eko ELEFT, issued May 11, 2020; [23]
• Certain Infusion Pumps and Infusion Pump Accessories, issued May 13, 2020; [24]
• G Medical Innovations Ltd.'s VSMS Patch, issued May 14, 2020; [25] and
• Everlywell Inc.'s Everlywell COVID–19 Test Home Collection Kit, issued May 15, 2020.[26]

Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15137 Filed 7–13–20; 8:45 am]

BILLING CODE 4164–01–P

COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that VentFree may be effective for emergency use by HCP in healthcare settings to treat adult patients by reducing disuse atrophy of the abdominal wall muscles, which may reduce the number of days of ventilator support in patients who require mechanical ventilation during the COVID–19 pandemic, and that the known and potential benefits of the such products, for such use, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[19] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized protective barrier enclosures may be effective at preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when caring for or performing medical procedures on patients who are known or suspected to have COVID–19 in healthcare settings and that the known and potential benefits of protective barrier enclosures, for such use, outweigh the known and potential risks of such product; and, (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[20] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Duke Decontamination System may be effective at decontaminating compatible N95 respirators for reuse by HCPs to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[21] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the PITU may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, and that the known and potential benefits of such products, when used by HCP for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID–19 requiring airborne or droplet isolation precautions in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, outweigh the known and potential risks of the PITU; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[22] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the use of the teleCARE IP Nurse Call System in healthcare environments may be effective for preventing COVID–19 exposure in healthcare providers by enabling remote communication between patients and healthcare providers, and, for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider. FDA concluded that the known and potential benefits of the teleCARE IP Nurse Call System, for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[23] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the ELEFT may be effective for use by HCP to provide an assessment of LVEF for use as a diagnostic aid to screen for potential cardiac complications associated with COVID–19 or underlying cardiac conditions that may affect clinical management of COVID–19, in adult patients having or suspected of having COVID–19 and that the known and potential benefits of ELEFT, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[24] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that authorized infusion pumps and infusion pump accessories may be effective for use by HCPs to treat conditions caused by COVID–19 with the controlled infusion of medications, TPN, and/or other fluids, and that the known and potential benefits of such products, for such use outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[25] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the VSMS Patchmay be effective in remotely monitoring QT interval prolongation on an ECG in patients who are undergoing treatment in a hospital setting for COVID–19 with drugs that can prolong QT intervals and may cause life-threatening arrhythmias (*e.g.,* hydroxychloroquine or chloroquine, especially when used in combination with azithromycin), the known and potential benefits of the VSMS Patch, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[26] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the home-collected human specimen, and that the known and potential benefits of the product when used for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1313]

Electronic Submissions; Data Standards; Support for Standard for the Exchange of Nonclinical Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) Center for Biologics Evaluation and Research (CBER) is announcing support for the current version of Clinical Data Interchange Standards Consortium (CDISC) Standard for the Exchange of Nonclinical Data (SEND) and an update to the FDA Data Standards Catalog for the submission of nonclinical data in new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs). This update does not apply to noncommercial INDs for a product that is not intended for commercial distribution (research and investigator-sponsored INDs); INDs and BLAs for devices that are regulated by CBER as biological products under the Public Health Services (PHS) Act; and submissions for blood and blood components, including Source Plasma.