March 24, 2020

To Manufacturers and Other Stakeholders:

This Emergency Use Authorization (EUA) is being issued in response to concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in healthcare settings to treat patients during the Coronavirus Disease 2019 (COVID-19)[1] pandemic.

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[2] Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[3]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories[4] that FDA determines meet the criteria for safety, performance and labeling set forth in Section II and Appendix A for emergency use in healthcare settings to treat patients during the COVID-19 pandemic, contingent upon submission of a request from the sponsor of a ventilator, ventilator tubing connector, or ventilator accessory as described in Section II and pursuant to the Conditions of Authorization in Section IV of this letter. Ventilators, ventilator tubing

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[1] On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19). The new names are used throughout this document.
[2] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 4, 2020) (accessible at https://www.fda.gov/media/135010/download).
[3] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, March 24, 2020.
[4] The ventilators, ventilator tubing connectors, and ventilator accessories that are eligible for inclusion under this EUA are those that are not currently marketed in the U.S., or that are currently marketed in the U.S. but a modification is made to the device that would trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, as set forth in the FDA's Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus.

connectors, and ventilator accessories that have been authorized will be added to this letter of authorization in Appendix B (referred to in this letter as "authorized ventilators, ventilator tubing connectors, and ventilator accessories").

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the authorized ventilators, ventilator tubing connectors, and ventilator accessories as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings to treat patients during the COVID-19 pandemic meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have 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 ventilators, ventilator tubing connectors, and ventilator accessories may be effective in treating patients during the COVID-19 pandemic, and that the known and potential benefits of such products, when used to treat patients during the COVID-19 pandemic, outweigh the known and potential risks of such products; and

3. There is no adequate, approved, and available alternative to the emergency use of the authorized ventilators, ventilator tubing connectors, and ventilator accessories for treating patients during the COVID-19 pandemic.[5,6]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of authorized ventilators, ventilator tubing connectors, and ventilator accessories listed in Appendix B for use in healthcare settings by patients during the COVID-19 pandemic.

Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories Eligible for Authorization under this EUA

[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[6] As COVID-19 continues to expand globally, the supply chain for ventilators that meet FDA regulatory requirements has been substantially stressed, with shortages already being observed in United States healthcare institutions, with demand exceeding available supply. These ventilators are an integral part of routine patient care and are critically important to treatment of patients in severe respiratory distress. Under the circumstances of this emergency, nationwide shortages are expected, and FDA is taking steps to address the observed and anticipated shortages of ventilators by providing regulatory flexibility for ventilators, ventilator tubing connectors, and ventilator accessories. In conclusion, there are not sufficient quantities of ventilators available that comply with FDA's regulatory authority to meet the needs of the United States healthcare system.

The ventilators, ventilator tubing connectors, and ventilator accessories that are eligible for inclusion under this EUA are those that are not currently marketed in the U.S., or that are currently marketed in the U.S. but a modification is made to the device that would trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, as set forth in the FDA's Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus. As noted in that guidance, the products that are currently marketed in the U.S. fall under the regulations and within the device types listed in **Table 1** (ventilators) or **Table 2** (ventilator tubing connectors and ventilator accessories).

Table 1. Ventilators

Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 868.5895	Ventilator, Continuous, Facility Use	CBK	II
	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	MNT	II
	Continuous, ventilator, home use	NOU	II
	Ventilator, continuous, minimal ventilatory support, home use	NQY	II
	Ventilator, continuous, non-life-supporting	MNS	II
	Mechanical Ventilator	ONZ	II
21 CFR 868.5925	Ventilator, Emergency, Powered (Resuscitator)	BTL	II
21 CFR 868.5160	Gas-machine, anesthesia	BSZ	II
21 CFR 868.5905	Ventilator, non-continuous (respirator) Including masks[7] and interfaces under the same product code	BZD	II
	Conserver, Oxygen	NFB	II

[7] This reference is limited to masks used with a ventilator and does not refer to personal protective equipment, such as surgical masks (21 CFR 878.4040).

	Device, Positive Pressure Breathing, Intermittent	NHJ	II
	Resuscitator, Manual, Non Self-Inflating	NHK	II
21 CFR 868.5454	High flow/high velocity humidified oxygen delivery device	QAV	II

Table 2. Ventilator Tubing Connectors & Ventilator Accessories

Classification Regulation	Device Type	Product Code[8]	Device Classification
21 CFR 868.5240	Anesthesia breathing circuit	OFP	I
	Anesthesia breathing circuit	CAI	I
21 CFR 868.5260	Filter, Bacterial, Breathing-Circuit	CAH	II
21 CFR 868.5270	Heated breathing circuit	BZE	II
21 CFR 868.5340	Cannula, Nasal, Oxygen	CAT	I
21 CFR 868.5440	Generator, oxygen, portable	CAW	II
21 CFR 868.5450	Humidifier, Respiratory Gas, (Direct Patient Interface)	BTT	II
21 CFR 868.5580	Mask, Oxygen	BYG	I
21 CFR 868.5730	Tube, Tracheal (W/Wo Connector)	BTR	II
	Airway Monitoring System	OQU	II
21 CFR 868.5895	Accessory to Continuous Ventilator (Respirator)	MOD	II
21 CFR 868.5965	Attachment, Breathing, Positive End Expiratory Pressure	BYE	II
21 CFR 868.5975	Set, Tubing and Support, Ventilator	BZO	I

Authorization Process

[8] For more information see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

To be added to Appendix B, ventilators, ventilator tubing connectors, and ventilator accessories must be determined to meet the applicable criteria for safety, performance and labeling set forth in Appendix A. FDA will add a ventilator, ventilator tubing connector, or ventilator accessory to the list of authorized products in Appendix B upon submission of a request from the sponsor as described below and after confirmation that the safety, performance and labeling criteria have been met, and pursuant to the Conditions of Authorization in this EUA. A sponsor may request the inclusion of any ventilator, ventilator tubing connectors, or ventilator accessory in Exhibit B by submitting a request to CDRH-COVID19-Ventilators@fda.hhs.gov that includes the following information:

1) 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 authorizations in the country of origin (or region) (if any).

2) A copy of the product labeling.

3) Whether the device currently has marketing authorization in another regulatory jurisdiction, such as the European CE Mark, Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion, Health Canada Licence, or Japan Pharmaceuticals and Medical Device (PMDA) approval (including certification number, if available).

4) Whether the device has been designed, evaluated, and validated in accordance with the applicable FDA-recognized standards identified in Appendix A.

5) 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.

6) Whether the device is manufactured in compliance with other internationally recognized quality management systems.

7) Whether the device is designed with a power supply that is compatible with United States voltage, frequency, and plug type standards or is accompanied by an appropriate power supply adapter for use in the United States.

8) Information sufficient to demonstrate that the device meets the criteria for safety, performance and labeling set forth in Appendix A.

Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories

Ventilators, ventilator tubing connectors, and ventilator accessories are authorized under this EUA and listed in Appendix B when FDA determines they meet the criteria for safety, performance and labeling set forth in this section (Section II) and Appendix A and that the terms and conditions of this Authorization have been met. Authorized ventilators, ventilator tubing connectors, and ventilator accessories are authorized to be manufactured and distributed to healthcare settings and used for treatment of patients under this EUA, despite the fact that such

products and their sponsors and distributors do not meet certain requirements otherwise required by applicable federal law.

Authorized ventilators, ventilator tubing connectors, and ventilator accessories listed in Appendix B must be accompanied by labeling developed by the sponsor that includes information specified in Appendix A. In addition, the authorized products must be accompanied by the following information pertaining to the emergency use (also described in Appendix A), which are authorized to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Emergency Use of Ventilators During the COVID-19 Pandemic
- Fact Sheet for Patients: Emergency Use of Ventilators During the COVID-19 Pandemic

The sponsor's developed instructions for use and the two fact sheets are referred to as "authorized labeling."

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized ventilators, ventilator tubing connectors, and ventilator accessories, when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized ventilators, ventilator tubing connectors, and ventilator accessories, may be effective in treating patients during the COVID-19 pandemic, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized ventilators, ventilator tubing connectors, and ventilator accessories when used to treat patients during the COVID-19 pandemic (as described in the Scope of Authorization of this letter (Section II)), meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of authorized ventilators, ventilator tubing connectors, and ventilator accessories under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section V). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), ventilators, ventilator tubing connectors, and ventilator accessories that are determined to meet the criteria for safety, performance and labeling set forth in this section (Section II) and Appendix A that are included in Appendix B are authorized to be used and distributed as set forth in this EUA.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain FDA Requirements

I am waiving the following requirements for authorized ventilators, ventilator tubing connectors, and ventilator accessories during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized ventilators, ventilator tubing connectors, and ventilator accessories listed in Appendix B that are used in accordance with this EUA; and

- Registration and listing requirements, including the requirements under 21 CFR Part 807.

IV. Conditions of Authorization

Pursuant to section 564(e) of the Act, I am establishing the following conditions on this authorization:

Sponsors of Authorized Products

1) Sponsors will make ventilators, ventilator tubing connectors, and ventilator accessories available with the authorized labeling.

2) Sponsors must comply with all applicable labeling requirements under the FD&C Act and FDA regulations, except for unique device identification requirements (see Subpart B of 21 CFR Part 801).

3) All descriptive printed matter relating to the use of the authorized ventilator, ventilator tubing connector, or ventilator accessories listed in Appendix B shall be consistent with the authorized labeling. No descriptive printed matter relating to the use of the authorized ventilator listed in Appendix B may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.

4) Sponsors will have a process in place for reporting adverse events of which they become aware to FDA per mandatory reporting requirements under 21 CFR Part 803. Adverse events of which the manufacturer becomes aware will be reported to FDA.

5) Sponsors will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

6) Through a process of inventory control, sponsors will maintain records of the healthcare settings to which they distribute the ventilators, ventilator tubing connectors, or ventilator accessories and the numbers of each such product they distribute.

7) Sponsors are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

8) Sponsors will notify FDA of any authorized distributor(s) of the product, including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA.

Authorized Distributor(s)[9]

9) Authorized distributor(s) will make ventilators available with the authorized labeling.

10) Through a process of inventory control, authorized distributor(s) will maintain records of the healthcare settings to which they distribute the ventilators and number of ventilators they distribute.

11) Authorized distributor(s) are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Conditions Related to Advertising and Promotion

12) All advertising and promotional descriptive printed matter relating to the use of the authorized ventilator, ventilator tubing connector, or ventilator accessory shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

13) No advertising or promotional descriptive printed matter relating to the use of the authorized ventilator, ventilator tubing connector, or ventilator accessory may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID pandemic.

14) All advertising and promotional descriptive printed matter relating to the use of the authorized ventilator, ventilator tubing connector, or ventilator accessory clearly and conspicuously shall state that:

- This ventilator, ventilator tubing connector, or ventilator accessory (as applicable) has not been FDA cleared or approved;
- This ventilator, ventilator tubing connector, or ventilator accessory (as applicable) has been authorized by FDA under an EUA;
- This ventilator, ventilator tubing connector, or ventilator accessory (as applicable) is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of ventilators, ventilator tubing connectors, and

[9] "Authorized Distributor(s)" are identified by the sponsor in EUA requests as an entity allowed to distribute the product.

ventilator accessories under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of ventilators, ventilator tubing connectors, and ventilator accessories during the COVID-19 pandemic is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

Appendix A. Criteria for Safety, Performance and Labeling

To be added to Appendix B, ventilators, ventilator tubing connectors, and ventilator accessories must be determined to meet the applicable criteria for safety, performance and labeling set forth below. FDA will add a ventilator, ventilator tubing connector, or ventilator accessory to the list of authorized products in Appendix B upon submission of a request from the sponsor as described in Section II and after confirmation that the applicable safety, performance and labeling criteria have been met, and pursuant to the Conditions of Authorization in this EUA.

Declarations of Conformity

Sponsors should provide declarations of conformance with the following standards as applicable:

- IEC 60601-1: 2012: *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2: 2014: *Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*
- IEC 60601-1-11: 2015: *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- Any other applicable collateral/particular standards in the IEC 60601-1: 2012 family
- IEC 62304: 2015: *Medical Device Software – Software Life Cycle Processes*
- AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ANSI/IEEE C63.27: 2017: *American National Standard for Evaluation of Wireless Coexistence*
- AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ISO 10993: Fifth Edition 2018-08: Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 18562-1 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process*
- ISO 18562-2 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter*
- ISO 18562-3 First Edition 2017: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds*
- ISO 18562-4 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 4: Tests for Leachables in Condensate*

In addition, sponsors should provide declarations of conformance with the following particular standards as applicable to the device:

- ISO 10651-5 First Edition 2006-02-01: *Lung Ventilators for Medical Use - Particular Requirements for Basic Safety and Essential Performance - Part 5: Gas-Powered Emergency Resuscitators*
- ISO 17510 First Edition 2015-08-01: *Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories*
- ISO 80601-2-12 First Edition 2011-04-15: *Medical Electrical Equipment - Part 2-12: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators [Including: Technical Corrigendum 1 (2011)]*
- ISO 80601-2-13 First Edition 2011-08-11: *Medical Electrical Equipment -- Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation [Including: Amendment 1 (2015) and Amendment 2 (2018)]*
- ISO 80601-2-69 First Edition 2014-07-15: *Medical Electrical Equipment - Part 2-69: Particular Requirements for Basic Safety and Essential Performance of Oxygen Concentrator Equipment*
- ISO 80601-2-70 First Edition 2015-01-15: *Medical Electrical Equipment - Part 2-70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnoea Breathing Therapy Equipment*
- ISO 80601-2-74 First Edition 2017-05: *Medical Electrical Equipment - Part 2-74: Particular Requirements for Basic Safety and Essential Performance of Respiratory Humidifying Equipment*
- ISO 80601-2-79 First Edition 2018-07: *Medical electrical equipment - Part 2-79: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Impairment*
- ISO 80601-2-80 First Edition 2018-07: *Medical Electrical Equipment - Part 2-80: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Insufficiency*

Device Specifications and Instructions for Ventilators and Accessories

Sponsors of ventilators, ventilator tubing connectors, and ventilator accessories should provide the following specification information.

For devices for delivering ventilatory support, sponsors should provide specific information and instructions regarding the device's:

- Available ventilation modes, patient interfaces, ventilatory parameter ranges (e.g., maximum inspiratory pressure, positive end-expiratory pressure, respiration rate, flow, delivered tidal volume, triggering, etc.)
- Battery specifications (if applicable), including runtime, how users are notified of device battery status (e.g., alarms), and expected use life that is supported by testing. For devices with external or replaceable internal batteries, the sponsor should provide information regarding chemistry, including information regarding design, capacity, and software and/or hardware risk mitigations for overcharging,

alarms, and information regarding conformance to applicable standards (e.g., IEC62311 for rechargeable batteries or IEC 60086-4 for non-rechargeable batteries for lithium-ion technology)
- Description of the device's alarm functionality, including a listing of all alarm conditions and the associated default settings and limits
- Description of the device's sensors and monitored parameters (including device parameters or patient parameters, as applicable)

For ventilator accessories sponsors should provide specific information and instructions (as applicable), regarding the device's:

- Connection dimensional characteristics (i.e., per ISO 5356-1) types (e.g. single limb with active exhalation, dual limb)
- Compensating controls

Reprocessing and Shelf-life Information

Sponsors of ventilators, ventilator tubing connectors, and ventilator accessories should provide the following information and instructions regarding device reprocessing.

- Instructions on how to reprocess reusable accessories, including filters and sensors[10]
- A list of all components—both internal and external to the ventilator—that can contact patient-expired gases or may become contaminated with patient bodily fluids. Such components may include, but are not limited to: the expiratory module, flow sensors, pressure sensors, humidifier, patient circuit, carbon dioxide module sensor. The list should specify whether the device components are intended for single use or are reusable. This applies to both patient-contacting components, as well as components that may otherwise come in contact or be contaminated with patient-expired gases or bodily fluids
- Information regarding device shelf-life

Facility Requirements (as applicable)

As applicable, sponsors of ventilators, ventilator tubing connectors, and ventilator accessories should provide the following information and instructions regarding the gas input and gas source of the device manufacturing facility.

- Gas input connection type (e.g., Diameter Index Safety System (DISS), NIST)
- Gas type (e.g., air, oxygen), including information regarding input pressures and flow rates
- Gas source (e.g., internal blower, wall-source)

[10] Such information is critical to ensuring that a device is appropriately prepared for its initial and subsequent uses. For recommendations regarding the development and validation of reprocessing instructions in your proposed device labeling, refer to FDA's guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

- Environmental controls to reduce transmission (e.g., negative pressure)

Labeling Requirements for Conditions of Use

The device's labeling includes the device's specifications (including ventilatory parameters), information regarding alarms (e.g., disconnect, EtCO2 alarms, etc.), device reprocessing instructions, and other instructions described above as applicable.

The Fact Sheet for Healthcare Providers administering the device includes the following:

- A statement that FDA has authorized the emergency use of the device;
- A description of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
- Information regarding the available alternatives to the device, including benefits and risks of the available alternatives.

The Fact Sheet for Patients to whom the device is administered includes the following:

- A statement that FDA has authorized the emergency use of the device;
- A description of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
- Information regarding the individual's option to accept or refuse administration of the device; of the consequence, if any, of refusing administration of the device; and of the available alternatives to the device, including the benefits and risks of the available alternatives.

Continuous Ventilator Splitters (Adapters for Multiplexing)

A. Engineering and Manufacturing Considerations:

Engineering and manufacturing considerations for a ventilator circuit adapter for multiplexing certain continuous ventilators intended for use in a healthcare facility (21 CFR 868.5895 and product code CBK (ventilator, continuous, facility use)) are set forth below.

These safety and performance considerations highlight the technical application of creating and testing this type of component and are not intended to be inclusive of all considerations. Sponsors should provide a description or discussion demonstrating their assessment of these considerations.

1. Material properties and high polymeric crosslinking/conversion
2. Material strength and durability
3. Gas pathway biocompatibility
    a. Dry gas validation would include:
        i. Testing for volatile organic compounds
        ii. Particulate matter sampling
4. Leak tests on finished product

5. Design for use of disconnect alarms that are on multiple circuit paths
6. Compliance with guidelines regarding standard for ventilator circuitry
    a. ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
    b. ISO 5366 First edition 2016-10-01 Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors
    c. ISO 18190 First edition 2016-11-01 Anaesthetic and respiratory equipment - General requirements for airways and related equipment
    d. ISO 18562-1 First Edition 2017-03: Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process
    e. ISO 18562-2 First Edition 2017-03: Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter
    f. ISO 18562-3 First Edition 2017: Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds
7. Appropriate labeling providing instructions for use and cautionary statements regarding the device use and recommended monitoring activities

B. Labeling Considerations:

The labeling conveys the following information:

1. A single ventilator fitted with the Vent Splitter can be used for multiple patients for ventilatory support during the COVID-19 pandemic when individual ventilators are not available or preemptively to increase the potential of single-use ventilators permitting mechanical ventilation for multiple patients simultaneously;
2. A description of the recommended use options/configuration (e.g. 2 splitters that can provide 2 ventilatory circuits (2 patients), 4 splitters that can provide 3 ventilatory circuits (3 patients) or 6 splitters that can provide 4 ventilatory circuits (4 patients); recommendations regarding the need for extra long tubing if needed to position patients in a manner that allows access to the patients and the ventilator; recommendations regarding free gas flow (FGF) requirements for oxygen when the ventilator used for multiple patients.
3. The pressure control mode is recommended when more than one circuit is added to the ventilator
4. The single ventilator fitted with the Vent Splitters will provide each patient with the same level of pressure support, the same rate of respiration, the same inspiratory/expiratory ratio, the same FiO2, the same level of PEEP, etc.
5. Because the single ventilator provides similar ventilatory support to all patients, it is

important to size match patients

6. Cautionary statement regarding the need for paralysis and sedation, and the need for additional infusion pumps to administer these agents, to avoid dyssynchronous breathing and system alarming from bucking and coughing;
7. Cautionary statement regarding the need for additional infusions pumps
8. Because the single ventilator provides similar ventilatory support to all patients, it is also important to select, to the extent possible, patients with similar underlying lung physiology, lung compliance, and ventilatory requirements, so that one system can generally meet each patient's needs, as they await individualized ventilators;
9. A description of recommended approach to patient monitoring, e.g. each patient should be assessed frequently clinically, at a minimum of 15-30 minute intervals, including vital signs, oxygen saturation level, end tidal Co2, examinations of the chest for bilateral air movement, and, if indicated, assessments of arterial blood gas findings to assure clinical stability on the shared system; close monitoring of all patients will be critical since they will likely be paralyzed and sedated.
10. If the shared ventilator alarms for any reason, clinical assessments of each patient are indicated immediately in order to determine which patient is triggering the alarm. The ventilator cannot indicate which patient is triggering the alarm. Providers need to assess all patients, consider suctioning and proper tube placement, and disconnect any unstable patient, considering mechanical bagging if necessary;
11. Potential infectious complications from sharing one ventilator have not been studied, and therefore caution is advised. If patients share the same infection, the single ventilator for multiple patients is a viable short-term management option. Each patient's is individualized with in-line filters designed to filter out viruses and/or bacteria and to protect the ventilator from contamination.