December 13, 2024

Zoll Medical Corporation
Jeffrey Churchill
Senior Manager, Regulatory Affairs
269 Mill Road
Chelmsford, Massachusetts 01824

Re: K233486
Trade/Device Name: 731 Series Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, DQA
Dated: December 11, 2024
Received: December 11, 2024

Dear Jeffrey Churchill:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director, Respiratory Devices Team
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233486

Device Name

731 Series Ventilator

Indications for Use *(Describe)*

Ventilation
Each model of the ZOLL 731 Series of Ventilators is indicated for use in the management of infant through adult patients weighing greater than or equal to 5 kg with acute or chronic respiratory failure or during resuscitation by providing continuous positive-pressure ventilation. ZOLL Ventilators are appropriate for use in hospitals, outside the hospital, during transport and in severe environments where they may be exposed to rain, dust, rough handling, and extremes in temperature and humidity. With an appropriate third-party filter in place, they may be operated in environments where chemical and/or biological toxins are present. When marked with an "MRI conditional" label, ZOLL ventilators are suitable for use in an MRI environment with appropriate precautions. ZOLL ventilators are intended for use by skilled care providers with knowledge of mechanical ventilation, emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation, and by first responders under the direction of skilled medical care providers.

Pulse Oximetry (SpO2)
The ZOLL Ventilator pulse oximeter with Masimo SET technology is intended for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate. The pulse SpO2 oximeter and accessories are indicated for use on adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, or in mobile environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

an Asahi Kasei company

269 Mill Road
Chelmsford, MA 01824
978.421.9655 *(main)*
978.421.0025 *(fax)*
zoll.com

510(K) SUMMARY

Sponsor Information:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824

Contact Person: Jeffrey Churchill
Associate Director, Regulatory Affairs
Phone: (339) 222-0524
Email: Jeffrey.Churchill@zoll.com

Date of Summary: December 13, 2024

Device Name and Classification:

510(k) Number: K233486
Trade/Proprietary Name: 731 Series Ventilator
Common Name: Transport Ventilator
Classification Name: Continuous Ventilator (21 CFR 868.5895)
Product Code: CBK, DQA

Predicate Device:

731 Series Ventilators (K162832, cleared 08/02/2017)
Regulation Number: 868.5895
Regulatory Class: Class II
Product Code: CBK, DQA

Device Description:

The ZOLL 731 Series Ventilators family consists of AEV, EMV+, Eagle II and Z Vent models which are small, durable, full-featured portable mechanical ventilators which provide ventilatory support for infants (≥ 5 kg), pediatric and adult patients. 731 Series ventilators are designed to operate in hospitals, prehospital, and field hospital settings. The ventilators can be operated from an AC or DC external power source, or from an integrated battery system, and support the following pressure and volume

ventilation modes: Assist/Control (AC), Synchronized Intermittent Mandatory Ventilation (SIMV) with or without Pressure Support (PS), Continuous Positive Airway Pressure (CPAP) with or without PS, with and without Noninvasive Positive Pressure ventilation (NPPV)/ Positive Pressure Ventilation (PPV).

The ventilator can use 6 ft or 12 ft patient circuits to support adult, pediatric, and infant patients. ZOLL provides the following circuit types:

- Pediatric/Adult, 6 ft and 12 ft, intended for use when delivering tidal volume from 200 ml to Adult.
- Infant/Pediatric, 6 ft and 12 ft, intended for use when delivering tidal volume from 50 ml to 300 ml.

The optional Oxygen Reservoir Kit can be used for the following purposes:

- Acts as a reservoir, collecting oxygen during the expiratory phase of ventilation.
- Provides an interface to the ventilator and the attachment of the low-flow oxygen supply hose.
- Provides an inlet in the event the low-flow oxygen supply fails, or the tidal volume is greater than the supplied oxygen.

Indications for Use:

Ventilation

Each model of the ZOLL 731 Series of ventilators is indicated for use in the management of infant through adult patients weighing greater than or equal to 5 kg with acute or chronic respiratory failure or during resuscitation by providing continuous positive-pressure ventilation. ZOLL ventilators are appropriate for use in hospitals, outside the hospital, during transport and in severe environments where they may be exposed to rain, dust, rough handling, and extremes in temperature and humidity. With an appropriate third-party filter in place, they may be operated in environments where chemical and/or biological toxins are present. When marked with an "MRI conditional" label, ZOLL ventilators are suitable for use in an MRI environment with appropriate precautions. ZOLL ventilators are intended for use by skilled care providers with knowledge of mechanical ventilation, emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation, and by first responders under the direction of skilled medical care providers.

Pulse Oximetry (SpO2)

The ZOLL ventilator pulse oximeter with Masimo SET technology is intended for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate. The pulse SpO2 oximeter and accessories are indicated for use on adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, or in mobile environments.

Comparison of Technological Characteristics:

The 731 Series Ventilator has been in the field for over 10 years. After the recent deployment and use of the ventilators with COVID-19 patients, care providers have identified specific areas for potential

improvement. Evolution in the standard of care has changed the level of patient sedation and patient management needs has motivated a comprehensive review of the pneumatic alarm system. This review focused on the patient-ventilator interaction which impacts alarm detection and the ventilator response to the alarm condition. As part of the current submission, ZOLL plans to update the ventilator software to revision 5.25 to improve the alarm logic specifically to target better functionality with COVID-19 patients.

The principles of operation are identical between the predicate ZOLL 731 Series Ventilator (K162832) and the proposed device. The indications for use remain the same from the predicate to the proposed ZOLL 731 Series Ventilator. The technological difference between the predicate device (K162832) and the proposed device is the introduction of software revision 5.25, which updates the ventilator alarm logic. Changes to the alarm logic were originally released under the FDA Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency as software revision 5.24, followed by intended commercialized software revision 5.25.

Under software revision 5.25, substantial equivalence has been determined to the predicate device, cleared under K162832. The following have been evaluated for substantial equivalence:

- Alarm System
- Functions and Features
- Indications for Use
- Intended Use
- Labeling
- Pulse Oximeter Specifications
- Ventilator Specifications

Substantial Equivalence – Non-Clinical Evidence:

The following performance data were provided in support of substantial equivalence determination:

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submission for Software Contained Medical Devices,* issued June 14, 2023. Extensive testing in the form of the software verification and system level validation ensured that the 731 Series Ventilators performs as well as the indicated predicate devices and met all its functional requirements and performance specifications.

Safety Testing per International Standards

The device was determined to be compliant with the following internationally recognized test standards as seen below in **Table 1**:

Table 1: 731 Series Ventilator Compliance Standards

FDA Consensus #	Standard Designation	Year
NR	EN 794-3	1998/A2:2009
5-134	EN ISO 15223-1	2021
15-135	ISO 20417	2021
19-4	EN 60601-1	2006/A1:2013
19-8	EN 60601-1-2	2014
5-132	EN 60601-1-6	2020
5-76	IEC 60601-1-8	2012
19-15	IEC 60601-1-12	2015
13-79	EN 62304	2006/A1:2016
5-129	EN 62366-1	2015+A1:2020
2-258	EN ISO 10993-1	2018
2-245	ISO 10993-5	2009
2-174	ISO 10993-10	2010
1-139	EN ISO 80601-2-61	2017
NR	EN ISO 13485	2016
5-125	EN ISO 14971	2019
1-103	ISO 5367	2014
NR	Mil-Std-810G	1/2000 with change C3 (5/2003)
NR	Mil-Std-461F	12/2007
NR	RTCA/DO 160	2010
19-33	IEC 62133-2	2017
NR	EN 1789	2007+A2:2014
19-45	AIM 7351731	Rev. 3.00 2021-06-04

Usability Testing

No usability validation is included in this plan. The user interface remains unchanged. There is no change in instructions on how to set alarms limits. There are no changes to alarm system audio annunciation, LED response and LCD indication (use of alarm message center, icon area and alarm flashing parameters).

Electrical Safety and electromagnetic compatibility (EMC)

The 731 Series Ventilator has been tested to meet applicable testing standards listed in **Table 1**.

Substantial Equivalence –Clinical Evidence:

Clinical evidence was not necessary to show substantial equivalence.

Conclusion:

As part of the change control process, the subject device has undergone the appropriate verification and validation testing, all of which confirms that the device meets its design, performance, and safety specifications. The information presented herein provides reasonable assurance of safety and effectiveness while following the least burdensome approach as defined in FDA's Guidance – *The Least Burdensome Provisions: Concept and Principles* published February 9, 2019. Performance data demonstrates that the features and functions of the subject device are substantially equivalent to those of the predicate device.