



August 2, 2017

Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Zoll Medical Corporation  
Chuck Kolifrath  
Regulatory Affairs Manager  
269 & 271 Mill Road  
Chelmsford, Massachusetts 01824-4105

Re: K162832  
Trade/Device Name: 731 Series Ventilators  
Regulation Number: 21 CFR 868.5895  
Regulation Name: Continuous Ventilator  
Regulatory Class: Class II  
Product Code: CBK, DQA  
Dated: July 13, 2017  
Received: July 14, 2017

Dear Chuck Kolifrath:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Mark S. Fellman -S**

for CDR Lori A. Wiggins, MPT, CLT  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K162832

Device Name  
731 Series Ventilators

### 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 (SpO<sub>2</sub>)

The ZOLL Ventilator pulse oximeter with Masimo SET technology is intended for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), and pulse rate. The pulse SpO<sub>2</sub> oximeter and accessories are indicated for use on adult and pediatric 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.

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## **510(k) Summary**

### **Sponsor Information:**

ZOLL Medical Corporation  
269 Mill Road  
Chelmsford, MA 01824

Contact Person: Chuck Kolifrath  
Regulatory Affairs Manager  
Phone Number: (978) 421-9786

**Date of Summary:** July 13<sup>th</sup>, 2017

### **Device Name and Classification:**

Common Name: Transport Ventilator

Device Name: 731 Series Ventilators

Classification Name: Ventilator, Continuous, Facility Use (21 CFR 868.5895)  
Oximeter (21 CFR 870.2700)

Product Code: CBK, DQA

### **Predicate Device:**

731 Series Ventilators (K111473)  
CareFusion ReVel Ventilator (K070594)  
Hamilton T1 Ventilator (K120670)  
CareFusion Avea Ventilator (K103211)

## Device Description:

The ZOLL 731 Series Ventilators family (acquired by ZOLL Medical Corporation through an asset acquisition of Impact Instrumentation, Inc. and reviewed and cleared under K111473) consists of AEV, EMV+ and Eagle II models which are small, durable, full-featured portable mechanical ventilators which provide ventilatory support for infants ( $\geq 5$  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).

As part of the current submission we are proposing to revise the device software to accomplish the following:

- Introduce Bilevel Mode Functionality
- Expanded Leak Compensation Functionality
- Introduce Start Menu Functionality
- Expanded Parameter Ranges
- Introduce Plateau Pressure (Pplat) Functionality
- Introduce Automatic Tubing Compensation Functionality
- Change Oxygen Supply Pressure Alarm Logic
- Introduce Inverse I:E Ratio Functionality

No hardware changes were made to the 731 Series Ventilators for the proposed software change.

## 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 (SpO<sub>2</sub>)

The ZOLL Ventilator pulse oximeter with Masimo SET technology is intended for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), and pulse rate. The pulse SpO<sub>2</sub> oximeter and accessories are indicated for use on adult and pediatric 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:**

Apart from the changes introduced as part of the proposed software release, the cleared functionality between proposed 731 Series Ventilator and the currently marketed 731 Series Ventilator (K111473) remains the same.

The table below lists the functionalities introduced with the proposed software update and identifies the predicate to which substantial equivalence has been established.

<b>Proposed Functionality</b>	<b>731 Series Ventilators (K111473)</b>	<b>CareFusion ReVel Ventilator (K070594)</b>	<b>Hamilton T1 Ventilator (K120670)</b>	<b>CareFusion Avea Ventilator (K103211)</b>
Bilevel Mode Functionality	✓			
Leak Compensation Functionality		✓		
Start Menu Functionality	✓			
Expanded Parameter Ranges			✓	
Plateau Pressure (Pplat) Functionality			✓	
Automatic Tubing Compensation Functionality				✓
Oxygen Supply Pressure Alarm Logic	✓			
Inverse I:E Ratio Functionality		✓		

No hardware changes were made to the 731 Series Ventilators for the proposed software change.

**Substantial Equivalence – Non-Clinical Evidence:**

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

*Software Verification and Validation*

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". The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could result in serious injury or death to the patient.

Extensive performance 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 of its functional requirements and performance specifications.

*Safety testing per the international recognized standards*

The device was evaluated and found to be in compliance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, EN 794-3, IEC 60601-1-8 and ISO 80601-2-61.

Safety testing ensures that the device complies with applicable sections of recognized industry and safety standards.

*Electrical Safety and electromagnetic compatibility (EMC)*

The proposed 731 Series Ventilators involves a software-only change to the 731 Series Ventilators (reviewed and cleared by the agency under K111473). The Electromagnetic Compatibility & Electrical Safety evaluation, established with the predicate 731 Series Ventilators (K111473) was not impacted by the proposed change.

*Usability Testing*

Usability testing was performed, where appropriate, to ensure that the proposed functionalities meet the user requirements and can be used as intended.

**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, validation and safety testing, all of which confirms that the device meets its design, performance, and safety specifications. Performance data demonstrates that the features and functions of the subject device is substantially equivalent to those of the indicated commercially distributed devices.