DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 18, 2017

ZOLL Medical Corporation
Ms. Pooja Dalvi
Regulatory Affairs Associate
269 Mill Road
Chelmsford, Massachusetts 01824-4105

Re: K170533
Trade/Device Name: Model 330 Multifunction Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: February 21, 2017
Received: February 23, 2017

Dear Ms. Dalvi:

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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170533

Device Name
Model 330 Multifunction Aspirator

Indications for Use *(Describe)*
The ZOLL® Model 330 Multifunction Aspirator is a self-contained suction device designed for removing debris from a patient's airway or respiratory system, secretions, blood, vomitus, surgical fluids, tissue (including bone), bodily fluids and infectious materials during surgery. Programmable intermittent gastrointestinal and abdominal wound drainage can also be performed with the device. It is suitable for use in pre-hospital, hospital, mass casualty and transport environments, including aeromedical. The Model 330 is only for use by or on the order of a physician.

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:

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Contact Person: Pooja Dalvi
Regulatory Affairs Associate
Phone: (978) 805-6293
Fax: (978) 421-0010

Date of Summary: April 17, 2017

Device Name and Classification:

Common Name: Aspirator

Device Name: Model 330 Multifunction Aspirator

Classification Name: Pump, Portable, Aspiration (Manual Or Powered)
(21 CFR 878.4780)

Product Code: BTA

Predicate Device:

Model 326/326M Aspirator (K951423)

Device Description:

The ZOLL Model 330 Multifunction Aspirator is a product based on the currently marketed Model 326/326M Aspirator (acquired by ZOLL Medical Corporation through an asset acquisition of Impact Instrumentation, Inc., reviewed and cleared under K951423). Similar to the currently marketed 326

Aspirator, the ZOLL 330 Aspirator is a small, durable, full-featured portable aspirator designed to operate in the hospital, prehospital, field hospital, mass casualty and during ground or air transport settings.

Like the predicate 326 Aspirator, the proposed 330 Aspirator is an electrically powered suction pump intended to remove debris from a patient's airway or respiratory system, secretions, blood, vomitus, surgical fluids, tissue (including bone), bodily fluids and infectious materials during surgery. Both the devices can also be used to perform programmable intermittent gastrointestinal and abdominal wound drainage.

Both Aspirators can be operated from an AC or DC external power source, or from an internal rechargeable battery system, and supports both aspiration modes: Continuous and Intermittent. The Continuous mode in the proposed 330 Aspirator is sub-divided into four procedure types: Surgical, Pharyngeal, Tracheal, and CASS (Continuous Aspiration of Subglottic Secretions). Each procedure has a pre-set pressure range under which the device can be operated. Additionally with the proposed device we have introduced the following functionality:

- ***Start Menu Functionality:*** Start Menu functionality is developed that allows the user to select from a series of preconfigured options that are appropriate for different patient groups: adult, pediatric, the last device settings and a custom start configuration established by the user or their organization.
- ***SMART FLOW Functionality:*** The feature detects a drop in the measured vacuum level when the therapy is not being applied and in response allows the aspirator to reduce the applied vacuum thereby allowing quieter operation of the device in the continuous mode.
- ***ALARMS:*** The 330 Aspirator offers a suite of visual alarm indicators by illuminating red, yellow and green LED lights, and audible alarm indicators, to alert the user about issues relating to external power or battery, environmental conditions that could affect device performance, and device self-check failures.

Indications for Use:

The ZOLL Model 330 Multifunction Aspirator is a self-contained suction device designed for removing debris from a patient's airway or respiratory system, secretions, blood, vomitus, surgical fluids, tissue (including bone), bodily fluids and infectious materials during surgery. Programmable intermittent gastrointestinal and abdominal wound drainage can also be performed with the device. It is suitable for use in pre-hospital, hospital, mass casualty and transport environments, including aeromedical. The Model 330 is only for use by or on the order of a physician.

Comparison of Technological Characteristics:

The Model 330 Multifunction Aspirator is substantially equivalent to the predicate device, the 326 Aspirator. The devices have the same intended use, operating mechanism, portability, and function. The minor differences between the subject and the proposed device are presented in the following table. These minor differences were appropriately assessed and do not raise new questions regarding safety or effectiveness. The comparison table is listed below,

Device	Model 326/326M Aspirator (K951423)	Proposed Model 330 Multifunction Aspirator	Substantial Equivalence Discussion
Regulation	21 CFR 878.4780	21 CFR 878.4780	Same
Classification	Class II	Class II	Same

Device	Model 326/326M Aspirator (K951423)	Proposed Model 330 Multifunction Aspirator	Substantial Equivalence Discussion
Product Code	Pump, Portable, Aspiration (Manual Or Powered)	Pump, Portable, Aspiration (Manual Or Powered)	Same
Intended Use	The Impact Model 326/326M is a self-contained, multipurpose, suction apparatus designed for removing secretions from the upper airway during oropharyngeal, nasopharyngeal and tracheal suctioning procedures; programmable gastrointestinal and abdominal wound drainage; or surgical site debris in field hospitals. The apparatus includes EMI/RFI suppression circuitry and is suitable for use in the desert, tropic, arctic or aeromedical environments. Simultaneous operation and battery recharge are permitted from either 115/230 VAC, 50-400 Hz using the provided AC-DC Power Supply or 12 VDC using the provided Auto Power Cable accessories. Simultaneous operation and/or recharge from aircraft electrical systems (24 to 28 VDC) is permissible with an appropriate cable. The Model 326/326M is designed to accept DC power sources ranging from 11 to 30 volts, positive or negative ground.	The ZOLL® Model 330 Multifunction Aspirator is a self-contained suction device designed for removing debris from a patient's airway or respiratory system, secretions, blood, vomitus, surgical fluids, tissue (including bone), bodily fluids and infectious materials during surgery. Programmable intermittent gastrointestinal and abdominal wound drainage can also be performed with the device. It is suitable for use in pre-hospital, hospital, mass casualty and transport environments, including aeromedical. The Model 330 is only for use by or on the order of a physician.	The Indications for Use has been revised for clarity.

Device	Model 326/326M Aspirator (K951423)	Proposed Model 330 Multifunction Aspirator	Substantial Equivalence Discussion
Energy Used	AC, DC and Internal Battery	AC, DC and Internal Battery	Same
Input voltage	AC: 115/230 VAC DC: 11 to 30 VDC	AC: 100 to 240 VAC DC: 11.8 to 30 VDC	Slightly expanded input power range.
Internal Battery	Sealed Lead Acid	Li-Ion	Li-Ion battery reflects the more modern and more commonly used technology.
Free Flow Rate	Continuous: Upto 30 LPM Intermittent: 8 l/min	Continuous: Upto 30 LPM Intermittent: 8 l/min	Same
Suction Pressure Range in Continuous Mode	0 mmHg to 550 mmHg.	10 mmHg to 550 mmHg	Pressure range remains effectively the same.
Suction Pressure Range in Intermittent Mode	0 mmHg to 200 mmHg	10 mmHg to 200 mmHg	Pressure range remains effectively the same.
Intermittent Controls: **ON Time** **OFF Time**	 5 to 40 sec 5 to 40 sec	 5 to 40 sec 5 to 40 sec	Same
Smart flow Feature	N/A	Yes	The feature is introduced to allow quieter operation of the device when the therapy is not being applied.
Alarms	N/A	Visual: Yes Audio: Yes	The proposed 330 Aspirator offers a suite of alarms to alert the user about issues relating to external power or battery, environmental conditions that could affect device performance, and device self-check failures.

Device	Model 326/326M Aspirator (K951423)	Proposed Model 330 Multifunction Aspirator	Substantial Equivalence Discussion
Smart Menu Functionality	N/A	Yes	Start Menu functionality is developed that allows the user to select from a series of preconfigured options that are appropriate for different patient groups.

Substantial Equivalence – Non-Clinical Evidence:

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

Software Verification and System 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 "minor" level of concern, since a failures or latent design flaws are unlikely to cause any injury to the patient or operator.

Extensive performance testing in the form of the software verification and system level validation ensured that the 330 Aspirator 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, IEC 62366-1, ISO 10079-1, IEC 60601-1-8, IEC 62133, IEC 62304 and IEC 60601-1-12.

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

Electrical Safety and electromagnetic compatibility (EMC)

The proposed Model 330 Multifunction Aspirator has been subjected to extensive performance and safety testing. Testing for Electromagnetic Compatibility & Electrical Safety was conducted in accordance with the applicable requirements and specifications contained in IEC 60601-1-2:2014, Medical Electrical Equipment- Part 1-2: General Requirements for Safety; Electromagnetic Compatibility.

Electrical safety testing was conducted in accordance with IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for Safety and Essential Performance.

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:

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.