July 18, 2018

ZOLL Medical Corporation
Pooja Dalvi
Regulatory Affairs Specialist
269 & 271 Mill Road
Chelmsford, Massachusetts 01824-4105

Re: K172653
Trade/Device Name: Power Infuser
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN
Dated: June 4, 2018
Received: June 5, 2018

Dear Pooja 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 and Part 809); 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

Digitally signed by Alan M. Stevens -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300189211, cn=Alan M. Stevens -S
Date: 2018.07.18 11:17:09 -04'00'

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172653

Device Name
Power Infuser

Indications for Use *(Describe)*
The Power Infuser® is intended for continuous or intermittent administration of therapeutic and clinically appropriate intravenous fluids, blood and packed red blood cells through clinically acceptable access points.
The device is intended for use by medical, paramedical and EMT personnel in the field and in pre-hospital and hospital environments.

When used with the Crystalloid/Colloid Cartridge the device is intended to deliver crystalloid and colloid resuscitative fluids. It is not intended to support the infusion of blood or blood products.
When used with the Blood Cartridge the device is intended to deliver crystalloid and colloid resuscitative fluids, whole blood and packed red blood.

The device is not intended to support the delivery of any pharmaceutical or other medications.

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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ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
U.S.A.

978-421-9655
978-421-0025 Main Fax

510(k) Summary

Sponsor Information:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824

Contact Person: Pooja Dalvi
Regulatory Affairs Specialist
Phone: (978) 805-6293
Fax: (978) 421-0010
Email: pdalvi@zoll.com

Date of Summary: July 18, 2018

Device Name and Classification:

Device Name: Power Infuser

Common Name: Infusion Pump

Classification Name: Infusion Pump (21 CFR 880.5725)

Product Code: FRN

Predicate Device:

Power Infuser, Model M100B-3A (K090736)

Device Description:

The ZOLL Power Infuser (reviewed and cleared with K090736) is a miniature battery-operated infusion pump designed for rapid intravenous fluid delivery in the field, in pre-hospital transport,

or in the hospital. The device supports two types of Power Infuser Cartridges, both of which are sterile and intended for single use:

- When used with the Crystalloid/Colloid Cartridge the device is intended to deliver crystalloid and colloid resuscitative fluids. It is not intended to support the infusion of blood or blood products.
- When used with the Blood Cartridge the device is intended to deliver crystalloid and colloid resuscitative fluids, whole blood and packed red blood cells.

The device, along with the cartridges, is not intended to support the delivery of any pharmaceutical or other medications.

Power infuser works on the principle of the shuttle pump mechanism wherein the tubing in the cartridges is squeezed (but not fully occluded) to allow the free flow of the fluid in the forward direction.

As a part of the current application we are proposing a material change to the tubing used in the Crystalloid/Colloid Cartridge and Blood Cartridge. The cleared DEHP Tygon tubing (S-40-HL Manufactured by Saint Gobain) has reached its end of life and we are proposing to replace it with the non-DEHP Tygon tubing (ND 100-40, manufactured by Saint Gobain).

The proposed material change is restricted to the Crystalloid/Colloid Cartridge and Blood Cartridge only. No changes has been made to the Power Infuser Pump as a result of the proposed change. The indications for use of the device, as described in the current application, has not changed as a result of the proposed modification.

No new accessories have been added, as part of the current submission, due to the proposed change. All the accessories offered with the ZOLL Power Infuser have been reviewed and cleared with the K090736.

Indications for Use:

The Power Infuser® is intended for continuous or intermittent administration of therapeutic and clinically appropriate intravenous fluids, blood and packed red blood cells through clinically acceptable access points.

The device is intended for use by medical, paramedical and EMT personnel in the field and in pre-hospital and hospital environments.

When used with the Crystalloid/Colloid Cartridge the device is intended to deliver crystalloid and colloid resuscitative fluids. It is not intended to support the infusion of blood or blood products.

When used with the Blood Cartridge the device is intended to deliver crystalloid and colloid resuscitative fluids, whole blood and packed red blood.

The device is not intended to support the delivery of any pharmaceutical or other medications.

Comparison of Technological Characteristics:

From a technological standpoint, the proposed Power Infuser is substantially equivalent to the predicate device, Power Infuser M100B3-A (K090736). The devices have the same intended use, operating mechanism, and function.

The only minor difference between the proposed Power Infuser and the currently marketed Power Infuser M100B3-A (K090736) is the material change to the tubing used in the Crystalloid/Colloid Cartridge and Blood Cartridge. The cleared DEHP Tygon tubing (S-40-HL Manufactured by Saint Gobain) has reached its end of life and we are proposing to replace it with the non-DEHP Tygon tubing (ND 100-40, manufactured by Saint Gobain).

Substantial Equivalence – Non-Clinical Evidence:

The proposed Power Infuser is identical to the currently marketed Power Infuser M100B3-A (K090736) except that there is a material change to the tubing used in the Crystalloid/Colloid Cartridge and Blood Cartridge. The cleared DEHP Tygon tubing has reached its end of life and we are proposing to replace it with the non-DEHP Tygon tubing. The intended use of the proposed Power Infuser device as described in the Indications for Use and labeling has not changed as a result of this submission.

Given the nature of the change, the validation testing in form of the Functional Test and Bio-compatibility test was performed. The device was evaluated and found to be in compliance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-24. Additionally, to evaluate the proposed material change, the device was further tested for accurate functioning of the air alarms, occlusion alarms and flow rate settings. Biocompatibility testing is performed in accordance with the FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Following bio-compatibility tests were performed to evaluate the new Tygon tubing:

- ISO 10993-5 Test for In Vitro Cytotoxicity
- ISO 10993-10 Test for Irritation and Skin Sensitization
- ASTM F 756-13 In Vitro Hemolytic Properties of Materials
- ISO 10993-11 Test for Acute Systemic Toxicity and Pyrogenicity Test
- ISO 10993-4 Selection of tests for interactions with blood (Complement Activation test, In-vitro Hemocompatibility test, and Partial Thromboplastin test)

The result of the Tygon Tubing Qualification and supplemental testing provide the evidence that the cartridges with the new tygon tubing meet the integrity and performance testing.

Substantial Equivalence –Clinical Evidence:

Clinical evidence was not necessary to show substantial equivalence.

Conclusion:

The information provided in this 510(k) demonstrates that the proposed Power Infuser is substantially equivalent to the predicate device, Power Infuser, Model M100B-3A cleared under K090736.