DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 15, 2017

RyMed Technologies, LLC
Ms. Anna McCutchen
Director of Quality Assurance and Regulatory Affairs
6000 W. William Cannon Drive B300
Austin, Texas 78749

Re: K162826
Trade/Device Name: Encore™ Neutral
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: May 19, 2017
Received: May 23, 2017

Dear Ms. Anna McCutchen:

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" (21CFR 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,

Lori A. Wiggins -S6

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
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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)*
K162826

Device Name
Encore™ Neutral

Indications for Use *(Describe)*
The Encore™ Neutral is intended for single patient use in intravenous and blood administrations and aspiration without the need for needles, thus eliminating the potential for needle-stick injuries during use.

The Encore™ Neutral may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec. The subject device does not have to be changed subsequent to use with a low pressure power injector.

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

Summary provided per [21 CFR 807.92]- K162826

Date: June 9, 2017

Submitter's Information:

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Device Name/ Trade Name: Encore™ Neutral

Common Name: Needleless IV Connector

Device Classification:
Regulation Number: 880.5440, Class II
Intravascular Administration Set
Classification Product Code: FPA
Panel: General Hospital

Predicate Device:
510(k) Number: K991653
Device Name: InVision-Plus® Injection Ports
Classification Product Code: FPA
Regulation Number: 880.5540, Class II
Applicant: RyMed Technologies, LLC

Description of the Device
The Encore™ Neutral is a luer activated needleless IV Connector that is disposable and for single patient use. It includes the following features:

- smooth swabbable surface
- tight seal integrity with no gaps or openings
- straight-through fluid pathway resulting in zero dead space
- 100% effective blood clearing
- neutral fluid displacement
- low priming volume
- saline-only flush option
- no clamping sequence or positive pressure syringe technique required

The Encore™ Neutral is a sterile single-use device which is provided individually packaged. The Encore™ Neutral is also provided bulk non-sterile, to be further processed (packaged and sterilized) by another manufacturer.

The Encore™ Neutral is available with an optional protective end cap attached to the male luer of the device.

The Encore™ Neutral is compatible with ISO 594 compliant male luer slip devices and male luer lock devices.

The Encore™ Neutral is composed of medical grade materials that are not made with Bisphenol A (BPA), di-2-ethylhexyl phthalate, diethylhexyl phthalate (DEHP) or natural rubber latex. The materials used have been subjected to and have passed biocompatibility testing per the latest ISO 10993 standards.

The Encore™ Neutral is MR Safe as it does not contain metallic, magnetic or metal components.

The Encore™ Neutral may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec. The device does not have to be changed subsequent to use with a low pressure power injector. When used with a low pressure power injector, the Encore™ Neutral must be secured with other devices rated for pressures up to 325 psi with a luer lock connection.

Indication for Use

The Encore™ Neutral is intended for single patient use in intravenous and blood administrations and aspiration without the need for needles, thus eliminating the potential for needle-stick injuries during use.

The Encore™ Neutral may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec. The subject device does not have to be changed subsequent to use with a low pressure power injector.

Substantial Equivalence

The Encore™ Neutral is substantially equivalent to the predicate device having similar indications for use, technological characteristics, and performance. Below is a device comparison between the Encore™ Neutral and the predicate device. In addition, RyMed Technologies, LLC has successfully conducted microbial ingress testing for up to 7 days or 300 activations, and sterilization, shelf life and packaging validations.

Characteristics for Substantial Equivalence (SE) Determination		
Characteristic	**Predicate Device (K991653)**	**Encore™ Neutral (subject device)**
FDA Regulation	21 CFR 880.5440 Intravascular Administration Set Class II Classification Product Code: FPA	21 CFR 880.5440 Intravascular Administration Set Class II Classification Product Code: FPA
Indications for Use	Intended for single patient use in intravenous and blood administration and aspiration without the need for needles, thus eliminating the potential for needle-stick injuries during use.	Intended for single patient use in intravenous and blood administration and aspiration without the need for needles, thus eliminating the potential for needle-stick injuries during use. Device may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec. The subject device does not have to be changed subsequent to use with a low pressure power injector.
Design	The predicate device is a luer activated needleless IV Connector The predicate device is disposable and for single patient use. The predicate device consists of a straight-through fluid pathway with zero residual volume (dead space), a smooth surface and is non-hemolytic (aspiration and injection).	The subject device is a luer activated needleless IV Connector The subject device is disposable and for single patient use. The subject device consists of a straight-through fluid pathway with zero residual volume (dead space), a smooth surface and is non-hemolytic (aspiration and injection).
Materials of Construction	The predicate consists of the following medical grade material types: Polycarbonate, polyethylene, polyiosprene, silicone rubber	The subject device consists of the following medical grade material types: Copolyester, MABS polymer, silicone rubber
Sterilization	The product Sterility Assurance Level (SAL) is 10^{-6} Method: Gamma and/or Ethylene Oxide	The product Sterility Assurance Level (SAL) is 10^{-6} Method: Gamma

Comparison

The following differences exist between the subject device and predicate device:

- The subject device indications for use includes use with power injection procedures
- The materials to construct the devices differ
- The subject device is validated for Gamma sterilization while the predicate device may be Gamma or Ethylene Oxide sterilized

The differences in the indications for use for the subject device and predicate device do not alter the intended use of the subject device. Both the subject device and predicate device are intended for intravenous and blood administration and aspiration.

The material differences between the subject device and predicate device do not adversely affect the safety and effectiveness of the subject device. All materials are medical grade and have passed biocompatibility testing.

Non-Clinical Data- Performance Testing

RyMed Technologies, LLC performed design verification performance testing to verify, demonstrate and support the claim of substantial equivalence to the predict device. All testing was conducted on the final finished sterile device.

The following standards were utilized in evaluating the functionality of the Encore ™ Neutral:

- ISO 594-1:1986, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements

- ISO 594-2:1998 Second Edition, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment- Part 2 Lock Fittings (General Plastic Surgery/General Hospital)

- ASTM F1608-16, Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)

- ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- AAMI/ANSI/ISO 11137-1: 2006/(R)2010, Sterilization of Health Care Products- Radiation- Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

- AAMI/ANSI/ISO 11137-2:2013, Sterilization of Health Care Products- Radiation- Part 2: Establishing the Sterilization Dose

The following performance tests were conducted according to internal procedures. All testing met the predetermined acceptance criteria and support the substantial equivalence determination:

- Activation Force
- Flow Rate at Gravity
- Fluid Displacement
- Multiple Activations
- Back Pressure
- Extended Access (Snap Back)
- High pressure (static conditions)
- Power Injection 10 mL/sec with maximum pressure of 325 psi
- Microbial Ingress
- Mechanical Hemolysis- Injection and Aspiration
- Blood Clearing

Biocompatibility

The materials of construction for the subject device were evaluated according to ISO 10993-1:2009 Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process.
All testing was conducted on the final finished sterile device. RyMed Technologies, LLC performed testing according to the following parts of the ISO 10993 Standard:

- ISO 10993-4:2002, Biological Evaluation of Medical Devices- Part 4: Selection of Tests for Interaction with Blood

- ISO 10993-5:2009, Biological Evaluation of Medical Devices- Part 5: Tests for InVitro Cytotoxicity

- ISO 10993-10:2010, Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization

- ISO 10993-11:2006-, Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity

Conclusion

It is concluded that based on performance data and biocompatibility testing conducted on the subject device along with the same intended use and similarities in indications for use and technological characteristics that the subject device is substantially equivalent to the predicate device.