April 20, 2020

ICU Medical, Inc.
Sheila Antonio
Senior Manager, Regulatory Affairs
951 Calle Amanecer
San Clemente, California 92673

Re: K192154
Trade/Device Name: Rio Vial-to-Bag Drug Reconstitution Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: March 23, 2020
Received: March 24, 2020

Dear Sheila Antonio:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

for Tina Kiang
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192154

Device Name

Rio™ Vial-to-Bag Drug Reconstitution Device

Indications for Use *(Describe)*

Rio™ Vial-to-Bag Drug Reconstitution Device is indicated for single-use reconstituting or mixing of liquid or lyophilized drug in a vial, and the aseptic transfer of the reconstituted drug into the multi-port LifeCare IV container system (IV bag) for patient infusion administration.

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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K192154 510(k) Summary

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92 for the **Rio™ Vial-to-Bag Drug Reconstitution Device.**

Submitter Information	
Company Name	ICU Medical, Inc.
Company Address	951 Calle Amanecer, San Clemente, CA 92673
Establishment Registration	2025816
Application Correspondent Name & Contact	Sheila Antonio, Senior Manager, Regulatory Affairs Phone: (949) 359-5708
Date prepared	March 23, 2020
Device Information	
Trade or proprietary name	Rio™ Vial-to-Bag Drug Reconstitution Device
Common or usual name	Binary Connector (Set, I.V. Fluid Transfer)
Regulation name	Intravascular Administration Set
Classification	Class II per 21 CFR 880.5440
Product Code(s)	LHI
Predicate Device - Legally marketed device(s) to which equivalence is claimed	
K090905, addEASE Binary Connector (by B. Braun Medical Inc)	
Reason for 510(k) submission	
The purpose of this submission is to demonstrate substantial equivalence of the new device, Rio™ Vial-to-Bag Drug Reconstitution Device to the legally marketed predicate device.	
Device Description	
Rio™ Vial-to-Bag Drug Reconstitution Device (Rio™) is a single use, sterile, two-way, drug transfer device that is designed and indicated to connect an ICU Medical LifeCare IV container system (IV bag)(up to 250 mL) via the drug additive port, to a drug vial having a 20mm stopper closure for reconstituting or mixing and aseptic transfer of the drug from the vial into the solution of the IV bag. Once connected, Rio™ is not separated from the IV bag or vial, and should be disposed of with the IV bag when administration is complete. Rio™ is intended to be used in a pharmacy setting or patient care area, by trained clinicians. Rio™ design consists of a port spike that connects to the compatible IV bag on one end, and a vial spike on the other end to connect a standard liquid or lyophilized/powdered drug vial having a 20mm closure. The bag spike and vial spike contain protective caps that maintain the sterility of the device until the caps are removed prior to use. Rio™ also includes a flow director (rotating handle) that will isolate the fluid between the vial and bag until manipulated by the pharmacist or clinician to allow two-way fluid transfer between the vial and bag. Rio™ is needlefree and will passively aid in the prevention of needlestick injuries.	
Indications for use	
Rio™ Vial-to-Bag Drug Reconstitution Device is indicated for single-use reconstituting or mixing of liquid or lyophilized drug in a vial, and the aseptic transfer of the reconstituted drug into the multi-port LifeCare IV container system (IV bag) for patient infusion administration.	

Summary of Technological Characteristics and Substantial Equivalence (Subject vs. Predicate)		
Feature	**Proposed Device** **Rio™ Vial-to-Bag Drug Reconstitution Device**	**Predicate Device** **K090905, addEASE Binary Connector (by B. Braun)**
Product Code	LHI Class II per 21 CFR 880.5440 *(Same as predicate)*	LHI Class II per 21 CFR 880.5440
Common Name	Set, I.V. Fluid Transfer *(Same as predicate)*	Set, I.V. Fluid Transfer
Intended Use	Reconstituting or mixing drug in vial with solution in IV bag *(Same as predicate)*	Reconstituting or mixing drug in vial with solution in IV bag
Indications for Use	Rio™ Vial-to-Bag Drug Reconstitution Device is indicated for single-use reconstituting or mixing of liquid or lyophilized drug in a vial, and the aseptic transfer of the reconstituted drug into the multi-port LifeCare IV container system (IV bag) for patient infusion administration.	The addEASE 20 mm Binary Connector with 17 Ga. Needle is a double ended transfer device intended for use in a pharmacy setting to connect a B. Braun 250mL Excel IV solution bag to a 20 mm drug vial for reconstituting or mixing the drug in the vial with the solution in the bag.
Principle of Operation	Two-way transfer device to connect drug vial to IV solution bag *(Same as predicate)*	Two-way transfer device to connect drug vial to IV solution bag
Mechanism of Action	Attaching device to drug vial and IV solution bag *(Same as predicate)*	Attaching device to drug vial and IV solution bag
Use Environment	Pharmacy setting and healthcare facility by trained clinician. *(Same as predicate)*	Pharmacy setting and healthcare facility by trained clinician.
Compatibility – Solution Bag	Multi-port ICU Medical LifeCare IV container system (up to 250 mL) *(Similar device access as predicate)*	B. Braun 250 mL Excel® IV solution bag
Compatibility – Drug Vial	Standard 20 mm closure drug vial (for liquid or powdered) *(Same as predicate)*	Standard 20 mm closure drug vial (liquid or powdered)
Materials of Construction	Bag spike – Plastic/ Polycarbonate *(Different than predicate)*	Bag spike – 17 Ga. Stainless Steel Needle
	Vial spike – Plastic/ Polycarbonate	Vial spike – Plastic (type unknown)
	Body – Polycarbonate *(Same base material as predicate)*	Body – Polycarbonate
	Handle – Polyethylene	N/A
	Protective Caps – Polyethylene (Bag Spike); PVC Tubing, Non-DEHP (Vial Spike) *(Same base material as predicate)*	Protective Caps (2) – Polyethylene

Biocompatibility	Per ISO 10993-1 *(Same as predicate)*	Per ISO 10993-1
Sterilization	E-beam radiation; SAL 10^{-6} *(Same SAL as predicate)*	Gamma radiation; SAL 10^{-6}
Pyrogenicity	Non-pyrogenic *(Same as predicate)*	Non-pyrogenic
Packaging	Individual, single-use; Sterile barrier packaging *(Same as predicate)*	Individual, single-use; Sterile barrier packaging

Comparison Summary

Rio™ utilizes the same fundamental drug transfer device technology as the predicate device, addEASE (K090905), to include equivalency in:

- intended use
- principles of operation
- mechanism of action
- intended use environments
- biocompatibility
- sterility
- pyrogenicity
- sterile barrier packaging

The main technological differences between Rio™ and the predicate device, addEASE (K090905), are as follows:

- Rio™ is needlefree and addEASE contains a stainless steel needle on bag spike end.
- Rio™ contains a directional turn handle to open and/or close fluid flow (“On” or “Off”) once assembled to a vial and bag, and addEASE has no flow director feature that allows for an ‘Off’ position. Rio™ and addEASE starts in an “Off” state. Once assembled and ready to use, Rio™ can be turned “On/Off” with the turn handle. The addEASE is actuated “On” and remains “On”.
- Rio™ and addEASE are compatible with company specific brands of IV solution bags.
- Rio™ is E-beam sterilized and addEASE is gamma sterilized. Each are radiation sterilized with the device provided in individual sterile barrier packaging.

These differences do not raise new questions of safety or effectiveness.

By design, Rio™ incorporates the existing ICU Medical vial spike and a modified bag (port) spike (cleared under K173477) to produce a two-way transfer device for directly connecting the drug vial to the IV solution bag. Modifications in the design composition and material of construction were made to the existing cleared components to integrate the body and turn handle with the bag and vial spikes into a single unit transfer device. Functionally, the Rio™ bag and vial spike features are equivalent to the reference device components cleared under K173477.

Performance Data: Non-Clinical Testing Summary

Non-clinical tests were conducted to support the safety of the device and demonstrates that the new device met its design specifications and performs as intended. The new device was subjected to the following functional and performance tests to demonstrate the device performs as intended:

- Functional Performance (per ISO 8536-4 and ISO 22413) including:
  - Positive pressure leak – dye solution tightness/air under water/pressure decay
  - Negative pressure leak
  - Fluid flow
  - Fragmentation/Coring
  - Insertion & Removal force
  - Retention Testing (Bag, Vial, & Fluid)
  - Vapor Barrier Test
- Particulate testing (per ISO 8536-4 and USP<788>)
- Chemical Compatibility
- Biocompatibility (per ISO 10993-1 for Externally Communicating Device with Blood Path, Indirect, Contact for a Prolonged Duration (> 24 hours to 30 days))
  - Hemocompatibility
  - Cytotoxicity
  - Sensitization
  - Irritation/Intracutaneous irritation
  - Acute Systemic Toxicity
  - Pyrogenicity
  - Subacute/Sub-Chronic Toxicity (Extractables per ISO 10993-18 with Toxicological Risk Assessment ISO 10993-17)
- Sterilization Validation (per ISO 11137)
- Packaging (per ISO 11607)
- Shelf life/Aging

Conclusion

Rio™ Vial-to-Bag Drug Reconstitution Device utilizes the same fundamental technology as the predicate device. The non-clinical testing and risk management demonstrates that the new device meets all design requirements and performance specifications, and does not raise new issues of safety or effectiveness when used as intended. Based on these data, Rio™ is deemed substantially equivalent (SE) to the predicate device.