DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

August 25, 2017

ICU Medical
Amy Giertych
Vice President, Global Regulatory Affairs
600 North Field Drive
Lake Forest, Illinois 60045

Re: K171346
Trade/Device Name: Sapphire Sets
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRZ
Dated: July 27, 2017
Received: July 27, 2017

Dear Amy Giertych:

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 (DICE) 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 (DICE) 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,

Tara A. Ryan -S

for
Lori 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

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)*

K171346

Device Name
Sapphire Set

Indications for Use *(Describe)*

Sapphire Primary Sets are indicated for the delivery of fluids from a container to a patient's vascular.

Sapphire Blood Sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient's vascular system.

Sapphire Epidural Set are indicated for the delivery of fluids to a patient's epidural space.

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

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92 for Sapphire Sets.

Submitter Information	
Name	ICU Medical
Address	600 North Field Drive Lake Forest, IL. 60046
Phone number	(224)-212-4235
Mobile number	(224)-507-8812
Fax number	(224) 212-5221
Establishment Registration Number	3005579246 (Owner/Operator #9063339)
Name of contact person	Amy Giertych, Vice President Global Regulatory Affairs
Date prepared	8/23/2017
Name of device	
Trade or proprietary name	Sapphire Sets
Common or usual name	Accessories, Pump, Infusion
Classification name	Infusion Pump, 21 CFR 880.5725, Class II
Product Code(s)	Primary Code: MRZ
Legally marketed device(s) to which equivalence is claimed	Sapphire Infusion System – K123049 (Primary Predicate 510(k)) Sapphire Sets – K160492 (Reference 510(k)) Plum Sets – K141789 (Reference 510(k))
Reason for 510(k) submission	New IV administration sets to be used with Q Core Medical Ltd.'s Sapphire Infusion System.
Device description	Sapphire Sets are intended for use with the Sapphire Infusion System. Sapphire sets are comprised of various components including the following: male luer adapter with cap, female luer with cap, piercing pin connector, sapphire cassette, tubing, flow control device, filter, in-line adapter, injection site assembly, check valve, pressure activated valve and blood chamber. Sapphire sets are configured to ensure the intended use of the device is met. The sets are disposable devices for single patient use.
Intended Use of Device	Sapphire sets are intended for use with the Sapphire Infusion System to deliver fluids from a container to a patient's vascular system.
Indication for use	Sapphire Primary Sets are indicated for the delivery of fluids from a container to a patient's vascular system. Sapphire Blood Sets are indicated for the delivery of fluids including but not limited to blood and blood products to a patient's vascular system. Sapphire Epidural Sets are indicated for the delivery of fluids from a container to a patient's epidural space.

Summary of the technological characteristics of the device compared to the predicate device		
Characteristic	**Predicate 510(k)**	**Proposed Device**
Indications for Use	The Q Core Sapphire infusion pump is intended for the controlled delivery through intravascular, subcutaneous, intra-arterial and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN), lipids, IV medication, epidural medication, blood and blood products. The Sapphire pump includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural. The pump is intended to be used by both licensed health care professionals in a clinical environment, and home users in an ambulatory environment. The Sapphire pump is designed to follow the patient through the various care areas, and is suitable for use in the different settings. The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.	Sapphire Sets are indicated for the delivery of fluids from a container to a patient's vascular system. Sapphire Blood Sets are indicated for the delivery of fluids including but not limited to blood and blood products to a patient's vascular system. Sapphire Epidural Sets are indicated for the delivery of fluids from a container to a patient's epidural space.
Characteristic	**Predicate/Reference 510(k)**	**Proposed Device**
Design and Materials of Construction	The design and materials of construction of all components for the sets, are as cleared under predicate/reference 510(k) noted below for each set component.	The design and materials of construction for all set components listed below have been previously cleared under the associated predicate/reference 510(k)
	Piercing Pin	**Piercing Pin**
	new	75-0704
	K160492 (reference 510(k))	85-0143
	K160492 (reference 510(k))	85-0142
	K160492 (reference 510(k))	85-0288
	K160492 (reference 510(k))	67-1760
	K160492 (reference 510(k))	90-5710
	Female Adapter	**Female Adapter**
	K160492 (reference 510(k))	90-9674
	Male Adapter	**Male Adapter**
	K160492 (reference 510(k))	85-0250
	Cap/Hood	**Cap/Hood**
	K160492 (reference 510(k))	75-0042
	K160492 (reference 510(k))	75-0735
	K160492 (reference 510(k))	75-2322
	K160492 (reference 510(k))	90-9664

Characteristic	Predicate/Reference 510(k)	Proposed Device
	K160492 (reference 510(k))	90-9665
	Cassette	**Cassette**
	K160492 (reference 510(k))	85-0239
	K160492 (reference 510(k))	67-2115
	Tubing	**Tubing**
	K160492 (reference 510(k))	75-0322
	K160492 (reference 510(k))	75-0324
	K160492 (reference 510(k))	75-0364
	K141789 (reference 510(k))	75-0941
	K160492 (reference 510(k))	75-5236
	Flow Control	**Flow Control**
	K141789 (reference 510(k))	67-1942
	K160492 (reference 510(k))	75-1004
	K160492 (reference 510(k))	75-1099
	K160492 (reference 510(k))	96-4509
	K141789 (reference 510(k))	96-4882
	In-Line Adapter	**In-Line Adapter**
	K141789 (reference 510(k))	75-4967
	K160492 (reference 510(k))	90-6979
	Injection Site	**Injection Site**
	K160492 (reference 510(k))	67-2060
	Check Valve	**Check Valve**
	K160492 (reference 510(k))	67-1042
	K160492 (reference 510(k))	67-1589
	Filter	**Filter**
	K141789 (reference 510(k))	67-1659
	K141789 (reference 510(k))	67-1721
	PAV	**PAV**
	K123049 (predicate 510(k)	67-2098
	Blood Chamber	**Blood Chamber**
	K141789 (reference 510(k))	85-0189
	Bonding Agents	**Bonding Agents**
	K160492 (reference 510(k))	52-0010
	K160492 (reference 510(k))	52-0013
	K160492 (reference 510(k))	52-0166

Summary of non-clinical tests for determination of substantial equivalence	All materials of construction for Q Core Sapphire Sets meet the applicable material test requirements for ISO 10993 as demonstrated in the predicate 510(k).	All materials of construction for Sapphire Sets remain the same as the predicate product. Additional data has been generated demonstrating that Sapphire sets meet the applicable material test requirements for ISO 10993 as follows: **ISO Standard** — **Biological Effect** 10993-4 Hemocompatibility 10993-5 Cytotoxicity 10993-10 Sensitization Intracutaneous Irritation 10993-11 Systemic Toxicity Subacute Toxicity Pyrogenicity
	Performance testing for all Q Core Sapphire set components was conducted as indicated in the predicate 510(k) to ensure the device performs as intended in accordance with applicable standards. All testing is acceptable.	New performance data has been generated to ensure the Sapphire Sets perform as intended in accordance with: ISO 8536-4. 6.1 Particulate Contamination ISO 8536-4. 6.2/ ISO 8536-8.6.3 Leakage ISO 8536-4.6.3 Tensile Strength ISO 8536-4.6.4 Coring ISO 8536-4.6.9 Flow Regulator ISO 1135-4.5.8 Flow Regulator Additionally, flow rate accuracy testing using the proposed Sapphire Sets and the Sapphire Infusion System has been conducted. All testing is acceptable.
	The product Sterility Assurance Level is 10^{-6} .	The product Sterility Assurance Level is 10^{-6} .

Conclusion

Sapphire Sets meet the functional claims and intended use as described in the product labeling. Sapphire Sets are substantially equivalent to the predicate device.