Q Core Medical Ltd.
% Rhona Shanker
President
Z & B Enterprises, Inc.
12154 Darnestown Road, #236
Gaithersburg, Maryland 20878

Re: K192860
Trade/Device Name: Sapphire Infusion Pump, Sapphire administration sets
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: FRN, MRZ, FPA
Dated: November 7, 2020
Received: November 10, 2020

Dear Rhona Shanker:

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,

Carolyn Dorgan
Acting Assistant Director, Infusion Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K192860

Device Name
Sapphire Infusion Pump, Sapphire administration sets

Indications for Use *(Describe)*
The Sapphire Infusion pump is intended for controlled delivery through intravascular, subcutaneous, intra-arterial, perineural and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN), lipids, IV medication, perineural medication, epidural medication, blood and blood products.

The Sapphire Infusion pump includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural.

It is intended to be used in the following environments of use: clinical, ambulatory, pre-hospital medical air and ground transportation and home. The pump is intended to be used by both licensed health care professionals and by lay users.

The Sapphire and the administration sets are indicated for use by both adult and pediatric populations.

The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

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
K192860

Manufacturer's Name	Q Core Medical Ltd. 29 Yad Haruzim St. Netanya 4250529 ISRAEL Ph: +972-73-2388888 Fax: +972-73-2388800
Corresponding Official:	Rhona Shanker FDA Regulatory Consultant to Q Core Medical Ltd
Telephone Number:	301-251-9570
E-mail:	rhonashanker07@verizon.net
Preparation Date:	November 19, 2020
Trade Name	Sapphire Infusion Pump, Sapphire Administration Sets
Common or Usual Name	Infusion Pump
Regulation Name	Infusion Pump
Regulation Number:	21 CFR 880.5725
Product Code:	FRN - Infusion pump MRZ - Infusion pump accessories FPA - Administration Sets
Device Class:	Class II
Predicate Device Infusion pump:	(K161667) Sapphire Infusion Pump
Predicate Device Administration sets:	(K141389) Sapphire administration sets, (K123049) Sapphire Administration Sets

Device Description

The Q Core Sapphire Infusion Pump is a single-channel, volumetric infusion pump. The SapphireInfusion Pump is intended for controlled delivery through intravascular, subcutaneous, intra-arterial, perineural and epidural routes. The pump is designed to deliver fluids such as Normal Saline, Total Parenteral Nutrition (TPN), lipids, IV medication, perineural medication, epidural medication, blood and blood products. The Sapphire Infusion 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 and lay users. The pump is intended to be used in the following environments of use: clinical, ambulatory, pre-hospital medical air and ground transportation and home use.

The dedicated Q Core Administration Sets for the Sapphire infusion pump are sterile and intended for single-patient use and single-use only.

The pump software includes the following infusion modes, but any one can be disabled: Continuous, Intermittent, TPN (Total Parenteral Nutrition), PCA (Patient Controlled Analgesia), Multi-Step and Epidural.

The Sapphire Infusion Pump offers an optional preprogrammed drug library which can be programmed using an additional software program "Drug library editor". The preprogrammed range limits are associated with certain drugs and/or certain modes and/or certain care areas.

Sapphire Infusion Pump accessories include the mini cradle, mini cradle with IPS, PCA lock boxes (100, 250, and 500ml), PCA/PCEA bolus handle, battery charger, battery case for extra battery source, administrations sets, a backpack, multi-pump mounting bracket, and an AC adapter.

Updates included in this submission:

1. **Addition of a new administration route** – Perineural
   Adding an administration route, Perineural, to the indications for use of the device. This update did not require any modification to the pump technology or design.
2. **Additional updates (catchup changes)** that did not change the basic functionality or technological characteristics of the pump or the administration sets
   - Software (SW) – e.g., minor enhancements, back to spec corrections, cybersecurity enhancements including implementation of digital code signing, reorganization of alarm priorities and audio and visual alarm characteristics, addition of low battery alarm at 10 minutes, addition of air-in-line alarm off option.
   - Pump cradle (accessory) added
   - Administration sets, including sets with NRFit connectors.
3. **Clarification of the indications for use statement**

Indications for Use

The Sapphire Infusion pump is intended for controlled delivery through intravascular, subcutaneous, intra-arterial, perineural and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN),lipids, IV medication, perineural medication, epidural medication, blood and blood products.

The Sapphire Infusion pump includes the following infusion modes for all intended uses: Continuous,

Intermittent,TPN, PCA, Multi-step, and Epidural.

It is intended to be used in the following environments of use: clinical, ambulatory, pre-hospital medical air and ground transportation and home. The pump is intended to be used by both licensed health care professionals and by lay users.

The Sapphire and the administration sets are indicated for use by both adult and pediatric populations.

The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

Substantial Equivalence Discussion

The table below includes a comparison of the intended use between the new device and those of the predicate device:

Characteristic	**Predicate Device** **Sapphire Infusion system** **(K161667)**	**Subject Device** **Sapphire Infusion Pump** **K192860**
Indications for Use	The Q Core Sapphire Infusion Pump is intended for 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 Infusion 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 and in pre-hospital medical air and ground transportation. The dedicated Q Core administration sets for the Sapphire Infusion Pump are intended for single-patient use and single use only.	The Sapphire Infusion pump is intended for controlled delivery through intravascular, subcutaneous, intra-arterial, perineural and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN),lipids, IV medication, perineural medication, epidural medication, blood and blood products. The Sapphire Infusion pump includes the following infusion modes for all intended uses: Continuous, Intermittent,TPN, PCA, Multi-step, and Epidural. It is intended to be used in the following environments of use: clinical, ambulatory, pre-hospital medical air and ground transportation and home. The pump is intended to be used by both licensed health care professionals and by lay users. The Sapphire and the administration sets are indicated for use by both adult and pediatric populations.

		The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use andsingle-use only.
Prescription or Over the Counter	Prescription	Prescription
Intended Population	Adult and pediatric	Adult and pediatric
Environment of Use	clinical, ambulatory, pre-hospital medical air and ground transportation, and home	clinical, ambulatory, pre-hospital medical air and ground transportation and home

The indications for use for the subject device is the same as the predicate device, with the addition of the perineural route. The addition of the Perineural administration route did not require any design change to the pump. After analysis of (i) clinical use, (ii) risk and (iii) drug route compatibility it was concluded that the current design can support this administration route without any design modifications and does not raise different questions of safety or effectiveness. The pump has been verified and validated through performance testing to meet this additional intended use.

The intended population for the subject device (adult and pediatric) is identical to the predicate device.

The environments of use for the subject device are identical to the predicate device.

Technological Characteristics

The table below includes a comparison of the technological characteristics between the new pump and those of the predicate pump. Flow rate accuracy and bolus accuracy are unchanged with the proposed device.

Technological Characteristic	**Predicate Device Sapphire Infusion system (K161667)**	**Subject Device Sapphire Infusion Pump K192860**	**Comments**
System Components/Features			
Real-time display	Yes	Same	NA
Microcomputer controlled pump	Yes	Same	NA
Internal clock	Yes	Same	NA
Administration Set	Yes	Same	NA
Air-in-line sensor	Yes	Same	NA
Occlusion sensor	Yes	Same	NA
Temperature Sensor	Yes	Same	NA
Number of Channels	1		NA
History Log	Yes	Yes	NA
Pump Alarms and Messages			
Battery/Low, Depleted	Yes	**Same, with the addition of a low battery alarm at 10 minutes.**	No effect on the pump safety or effectiveness

Technological Characteristic	Predicate Device Sapphire Infusion system (K161667)	Subject Device Sapphire Infusion Pump K192860	Comments
			(see Note #1 below)
Pump in stop mode (unattended)	Yes	Same	NA
High pressure (Upstream/ Downstream Occlusion)	Upstream -0.4bar Downstream 1.2 bar	Same	NA
Pump Fault	Yes	Same	NA
Low volume in medication reservoir	Yes	Same	NA
Cassette detachment /misplaced/door open	Yes	Same	NA
Air-in-line	Yes	Same	NA
Flow Error	Yes	Same	NA
Key stuck	Yes	Same	NA
End-of-Infusion	Yes	Same	NA
Programmable End-of-Infusion alarm	Yes	Same	NA
Programming Functions			
High Internal Temperature	Yes	Same	NA
Delivery Mode	Yes	Same	NA
Infusion Options	Yes	Same	NA
Security and/or Lock Levels	Yes	Same	NA
Demand Dose Lockout	Yes	Same	NA
Delivery Limit	Yes	Same	NA
Air Detection	Yes	**Yes, with option to disable by technician**	No effect on the pump safety or effectiveness (see discussion # Note 2 below)
Piggy back/Secondary	Yes	Same	NA
Delayed Start	Yes	Same	NA
Infusion Specifications			
Flow rate accuracy	Ave: 2.5% (-3.6% at 5-15°C to +3.5% at 30-40°C)	Same	NA
Minimum Continuous Delivery Rate	0.1 mL/hr	Same	NA
Maximum Continuous Delivery Rate	999 mL/hr	Same	NA

Technological Characteristic	Predicate Device Sapphire Infusion system (K161667)	Subject Device Sapphire Infusion Pump K192860	Comments
Minimum Intermittent Delivery Rate	0.1 mL/hr	Same	NA
Maximum Intermittent Delivery Rate	999 mL/hr	Same	NA
Minimum PCA Delivery Rate	0 mL/hr	Same	NA
Maximum PCA Delivery Rate	99.9 mL/hr	Same	NA
Minimum TPN Delivery Rate	0.1 mL/hr	Same	NA
Maximum TPN Delivery Rate	600 mL/hr	Same	NA
Minimum Epi Delivery Rate	0.1 mL/hr	Same	NA
Maximum Epi Delivery rate	200 mL/hr	Same	NA
Patient Demand Dose	Yes	Same	NA
Bolus Accuracy	Ave: 2.5% (-7.5% to 7.5% at 0.1mL/h)	Same	
Maximum Patient Demand Dose	20 mL	Same	NA
Clinician Bolus	Yes	Same	NA
Maximum Clinician Bolus	30 mL	Same	NA
Maximum Epidural Hourly Volume	60 mL/hr	Same	NA
Maximum Boluses per Hour	60 per hour / 60 per 4 hours	Same	NA
KVO	Yes	Same	NA
KVO Rate	0 – 20 mL/hr or the actual rate, whichever is lower	Same	NA
Reservoir volume	0.1 to 9999 mL	Same	NA
Dose lockout time	Yes	Same	NA
Dose per Hour Limit	Yes	Same	NA
Delivery Limit	Yes	Same	NA
Programmable Maximum Delivery Rate (Continuous Rate and Bolus)	Yes	Same	NA
Accessories			
Administration sets	Yes - Q Core supplied administration sets	Same	NA
AC adapter	Yes	Yes Same	NA
Remote Dose Cord	Same Yes	Yes Same	NA
Reservoir enclosure (Lockbox)	Yes (100, 250, 500)	Same	NA
Pole mount bracket	**Yes**	**Same, with an embedded power**	No effect on

Technological Characteristic	Predicate Device Sapphire Infusion system (K161667)	Subject Device Sapphire Infusion Pump K192860	Comments
(mini cradle)		**supply**	the pump safety or effectiveness (see discussion #3 below)
Pump Pouch	Yes	Same	NA
Multi-pump mounting bracket	Yes	Same	NA
Battery case	Yes	Same	NA
Electrical Safety			
Electrical Safety	Compliant with IEC 60601-1	Same	NA
Electromagnetic compatibility	Compliant with IEC 60601-1-2	Same	NA
Mechanical and Power Specifications			
Pump Size	143 x 96 x 49 mm (5.63 x 3.78 x 1.93 inches) HxWxD	Same	NA
Pump Weight	518 g (18.27 oz.), including battery	Same	NA
Power Sources	Rechargeable Li-Ion Battery 7.4V/1960 mAh; AC adapter Input: 100-240 AC; 50-60 Hz	Same	NA
Operating Environment			
Temperature	+5°C to 40°C (41°F to 104°F)	Same	NA
Relative Humidity	15% to 95%	Same	NA
Storage Environment			
Temperature	- 40°C to + 70°C (-40°F to 158°F).	Same	NA
Relative Humidity	15% to 95%	Same	NA

Comments regarding differences:

1. 10-minute low battery alarm

This high priority alarm was added as an additional "intermediate" alarm informing the user that battery is getting closer to depletion state (between the existing 30-minute low priority alarm to the high priority 3 minutes alarm before depletion). The alarm new alarm was verified and validated as part SW V&V and meet the requirements of IEC 60601-1-8.

2. Ability to turn off the air detection

The modification was implemented after analysis of (i) clinical use, (ii) risk and (iii) review of the market for similar cleared devices with same feature.

This feature was verified and validated as part SW V&V and also as part of Human Factors tests, concluding that this change it does not raise different questions of safety or effectiveness.

3. Pole mount (Mini Cradle) with an embedded power supply

This configuration is made as a combination of a power supply and the Mini Cradle (for simpler integration with the pump), resulting in an accessory which reduces user interactions with the same end result, i.e. mounting the pump on a pole and charging it. The same functions were retained, and testing demonstrates that it does not raise different questions of safety or effectiveness.

This accessory was tested for performance and along with the pump to meet the requirements of Electrical Safety (IEC 60601-1) and EMC (IEC 60601-1-2 and IEC 61000).

4. Cybersecurity

Additional changes were made to authentication and authorization controls, digital code signing, and other security controls to enhance the security of the device.

The table below includes a comparison of the technological characteristics between the new administration sets and those of the predicate administration sets.

Technological characteristic	**Predicate - Sapphire Administration Sets (K123049, K141389)**	**Subject Device – Sapphire Administration Sets**	**Safety and effectiveness implication**
Intended to be used only with the Q Core Infusion Pumps	Yes	Same	NA
Administration Cassette	Yes	Same	NA
Cassette safety feature	Anti-Free Flow Valve	Same	NA
Different configurations of the Sets are available, depending upon the required use	Yes	Same	NA
Different configurations available, and consist of conventional components	Yes	**Same, with the addition of the NRFit connector**	No effect on the pump safety or effectiveness (see discussion #5 below).
Contain sleeves to connect components	Yes	**No**	No effect on the pump safety or effectiveness (see discussion #6 below).
Sterile, single patient	Yes	Same	NA
Non-DEHP, latex free	Yes	Same	NA
Biocompatible materials	Yes	Same	NA
Non-pyrogenic	Yes	Same	NA
Set length	Up to 280 cm	**Up to 300 cm**	No effect on the pump safety or effectiveness (see
Priming volume	Up to 20 ml	**Up to 30 ml**	

			discussion #7 below)

Comments regarding differences between the administration sets

5. NRFit connector addition

ISO 80369-6: 2016 compliant connectors were added to administration sets for Neuraxial. Verification and validation of the connectors concluded that this modification does not alter their safety and effectiveness.

6. Sleeve removal

Removal of the sleeve component within the assembly resulted in a simpler and more cost-effective connection of set components, with reduced assembly work time. This modification did not include any change to the sets materials. Verification and Validation of the sets performance concluded that this modification does not alter their safety and effectiveness.

7. Length and priming update

The minimal length and priming volume update have no effect on the set performance or use. This modification did not include any change to the sets materials. Verification and Validation of the sets performance concluded that this modification has no implication on the safety and effectiveness**.**

There are no technological differences between the subject and predicate devices. All updates were evaluated for risk and fully verified and validated, confirming safety and effectiveness are maintained as in the predicate devices. The description of these changes is included in the device description and is presented in the Substantial Equivalence Discussion.

Performance Testing

The following bench testing was performed and reviewed to support the substantial equivalence of the subject device:

Software	• Software verification and validation per the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) for a Major Level of Concern • FDA Guidance "Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices"
Electrical safety	Electrical Safety per IEC 60601-1; 2012
EMC	EMC testing per IEC 60601-1-2; 2014
Alarms	Alarms per IEC 60601-1-8; 2012
Device Performance	• FDA Guidance "Infusion Pumps Total Product Life Cycle" • Accuracy testing under anticipated environments of use and routes • Administration sets performance testing per ISO 80369-6:2016
Battery safety	IEC 62133-2; 2017 compliance
Biocompatibility	Sub-chronic testing per ISO 10993-11:2017 (Administration sets)
Accessory compatibility	Verification that the pump is compatible with the IPS
Human Factors	Human factors studies per the FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016). The human

	factors studies were conducted with the intended user population, use environment and use scenarios to simulate clinical conditions. Results of the human factors testing demonstrate validation of the device per the intended use.
Cybersecurity	Cybersecurity was evaluated per the FDA Guidance Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff, (October 2, 2014). Specifically, addressing the following areas: Identify and Protect, Detect, Response and Recover
Reprocessing/Cleaning	Validation per the FDA Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015) confirmed cleaning and disinfection instruction provided in instructions for use
MR Safety	ASTM F2503-13, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment."

A safety assurance case is provided for the Sapphire Infusion System (pump, sets and accessories) as recommended in the FDA guidance document, Infusion Pumps Total Product Life Cycle.

The stated goal of the safety assurance case is:

- Device design is adequately safe for its intended use

The assurance case defined the device system, including the indications for use, system definition, operational description, patient populations, and use environments. The supporting assurance arguments covered the following attributes:

- The device is properly identified and defined
- The device design is adequately verified and validated
- The device risks are acceptably mitigated
- The device is adequately reliable to ensure its safety over its intended use life.

The specific evidence included within the assurance case to demonstrate the subject device is verified and validated for its intended use and to demonstrate substantial equivalence to the predicate devices is described in the table above.

Clinical tests

Not applicable. No clinical studies were conducted in conjunction with this application.

Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness.

The Sapphire Infusion system (pump, sets and accessories) is substantially equivalent to the Sapphire Infusion Pump cleared under K161667 (infusion pump) and accessories cleared under K123049, K141389 with respect to the indications for use, target populations, thebasic infusion pump hardware and software used to control delivery of the infusion, technological characteristics, the delivery

modes and safety features.

The modifications pertain to addition of Perineural administration route, extended administration sets portfolio, software updates and an additional accessory. There are no changes the basic infusion pump technology.

QCORE medical

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