March 12, 2026

Spectrum Medical S.r.l.
Raffaella Tommasini
Spectrum Medical Group Regulatory and Quality Director
via di Mezzo, 23
Mirandola, Modena 41037
Italy

Re: K252541
Trade/Device Name: Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary Bypass Heat Exchanger
Regulatory Class: Class II
Product Code: DTR
Dated: January 28, 2026
Received: January 28, 2026

Dear Raffaella Tommasini:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Meaghan Erlewein -S

For Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252541

Please provide the device trade name(s).

Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W

Please provide your Indications for Use below.

Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W is intended to be used with a compatible Heater/Cooler system to heat/cool blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration with a maximum flow rate of 3.0 l/min.

Device is intended for pediatric patients (BSA according following characteristics: 0.6 m2 < BSA < 1 m2)

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY

I. SUBMITTER

Submitter Name:	Spectrum Medical S.r.l.
Submitter Address:	Via di Mezzo, 23 41037 Mirandola (MO) Italy
Contact Person:	Raffaella Tommasini, Spectrum Medical Group Regulatory and Quality Director
Phone:	+39 0535 1803050
e-mail:	raffaella.tommasini@spectrummedical.com
Fax:	+39 0535 1803051
Date Summary Prepared:	March 6th, 2026

II. DEVICE

Proprietary Name:	Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W
Common Name:	Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W
Classification Name:	21 CFR 870.4240 Cardiopulmonary bypass heat exchanger
Regulatory Class:	II
Product Code:	DTR
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)

III. PREDICATE DEVICES

PRIMARY PREDICATE

Proprietary Name:	AMG PMP Pediatric
Common Name:	AMG PMP Pediatric
Classification Name:	21 CFR 870.4350 Cardiopulmonary Bypass Oxygenator
Regulatory Class:	II
Product Code:	DTZ
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
510(k) Number:	K202206

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PREDICATE/REFERENCE DEVICE

Proprietary Name:	Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4
Common Name:	Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W
Classification Name:	21 CFR 870.4240 Cardiopulmonary bypass heat exchanger
Regulatory Class:	II
Product Code:	DTR
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
510(k) Number:	K223879

IV. DEVICE DESCRIPTION

Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W is designed to manage the temperature of blood during surgical procedures requiring cardiopulmonary bypass (CPB) for periods lasting less than 6 hours.

The device is designed to:
- keep circulating blood at a specific temperature, depending on the type of surgery being performed;
- maintain blood/patient thermoregulation during the CPB;
- rewarm blood at the conclusion of the CPB in order to restore normothermic patient condition.

Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W has been designed to be powered by heater-cooler systems that use
- Water, or
- Glycol-based solution

as Heat Transfer Fluid (HTF).

V. INTENDED USE / INDICATIONS FOR USE

Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W is intended to be used with a compatible Heater/Cooler system to heat/cool blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration with a maximum flow rate of 3.0 l/min.
Device is intended for pediatric patients (BSA according following characteristics: 0.6 m^2 < BSA < 1m^2).

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device	Proposed Device – Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W	Predicate Device – AMG PMP Pediatric (K202206)	Reference Device - Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 (K223879)
Name	Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W	AMG PMP Pediatric	Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4
510(k) Number	K252541	K202206	K223879
Regulation #	870.4240	870.4350	870.4240
Regulation Name	Cardiopulmonary bypass heat exchanger	Cardiopulmonary Bypass Oxygenator	Cardiopulmonary bypass heat exchanger
Product Code	DTR	DTZ	DTR
Classification	II	II	II
Indication for Use	Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W is intended to be used with a compatible Heater/Cooler system to heat/cool blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration with a maximum flow rate of 3.0 l/min.	The device is indicated for patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for six hours or less with a maximum blood flow rate of 4 liters/minute.	The Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 is intended to be used with a compatible Heater/Cooler system to heat/cool blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

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Device	Proposed Device – Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W	Predicate Device – AMG PMP Pediatric (K202206)	Reference Device - Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 (K223879)
Target population	Pediatric patients (Body Surface Area according following characteristics: 0.6 m^2 < BSA < 1m^2).	Pediatric / small adults.	Adults
Target User	Perfusionist.	Perfusionist.	Perfusionist.
Biocompatibility requirements	In compliance with ISO 10993 series.	In compliance with ISO 10993 series.	In compliance with ISO 10993 series.
Main Contacting Materials	- Polycarbonate; - Stainless Steel; - Epoxy resin; - Phosphorylcholine coating.	For Heat Exchanger integrated in the Oxygenator: - Polycarbonate; - Stainless Steel; - Polyurethane resin; - Phosphorylcholine coating.	- Polycarbonate; - Stainless Steel; - Epoxy resin; - Phosphorylcholine coating.
Type of conductive material	Stainless Steel	Stainless Steel	Stainless Steel
Cooling/heating fluid	Water or glycol-based solution	Water	Water or glycol-based solution
Priming Volume	24 ± 2.5 ml	190 ml (Oxygenator + Heat Exchanger)	24 ± 2.5 ml
Max Flow Rate	3.0 l/min	4.0 l/min	3.0 l/min
Inlet/Outlet Blood Connector	1/4'' barbed (6.35 mm) 1/4'' barbed (6.35 mm)	3/8" barbed connectors	1/4'' barbed (6.35 mm) 1/4'' barbed (6.35 mm)

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Device	Proposed Device – Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 W	Predicate Device – AMG PMP Pediatric (K202206)	Reference Device - Quantum PureFlow Standard Heat Exchanger Medium Flow 1/4 (K223879)
Inlet/Outlet Cooling/Heating Fluid Connector	CPC HFC profile	1/2" Hansen quick couplings	CPC HFC profile
Single-use	Yes.	Yes.	Yes.
Sterile Condition	Sterile.	Sterile.	Sterile.
Sterilization Method	EtO sterilization	EtO sterilization	EtO sterilization

Table 1 – Comparative Data with Predicate and Reference Devices

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VII. PERFORMANCE DATA

NON-CLINICAL TESTING

As subject device is substantially equivalent to reference device (K223879) except for target population, all previously available data about non-clinical testing has been considered as still valid, in terms of:

- Performance evaluation according to ISO 7199:2016 [Recognition Nr. 3-150] (*only for sections applicable to Heat Exchangers);*
- Validation of the EtO Sterilization process, according to ISO 11135:2014 [Recognition Nr.: 14-529],
- Packaging Validation tests according to ISO 11607-1:2019 [Recognition Nr. 14-530];
- Biocompatibility of the finished product (worst case condition), according to International Standard ISO 10993-1:2018 [Recognition Nr. 2-258] and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The following tests for evaluation of devices' performances have been performed:

- Hemolysis test;
- Pressure drop test;
- Heat transfer efficiency.

In addition, updated data supporting claimed shelf-life have been included.

Animal Study

No animal studies have been performed to support changes object of the present 510(k).

CLINICAL TESTING

No clinical testing has been performed to support changes object of the present 510(k).

VIII. CONCLUSIONS

Based on evaluation of indications for use and technological characteristics, the proposed device has been demonstrated to be appropriate for its intended use and is considered substantially equivalent to predicate and reference devices (K202206 and K223879 respectively).