June 24, 2025

Spectrum Medical S.r.l.
Raffaella Tommasini
QA&RA Director
Via di Mezzo, 23
Mirandola, MO 41037
Italy

Re: K250326
Trade/Device Name: Quantum Perfusion Centrifugal Blood Pump CP22NG with Integrated Sensors (CP22V-NG)
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-Type Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: May 30, 2025
Received: May 30, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

Kathleen M. Grunder -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250326

Device Name

Quantum Perfusion Centrifugal Blood Pump CP22NG with Integrated Sensors (CP22V-NG)

Indications for Use *(Describe)*

The Quantum Perfusion Centrifugal Blood Pump CP22NG with Integrated Sensors indicated for use exclusively with Spectrum Medical Systems is intended to pump the blood through an extracorporeal circuit and to monitor pressure for periods lasting less than 6 hours for the purpose of providing either:

(i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or

(ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Device is intended for adult patients.

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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K250326

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, QA&RA Director – Spectrum Medical S.r.l.
Phone:	+39 0535 1803050
e-mail:	raffaella.tommasini@spectrummedical.com
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Date Summary Prepared:	February 3rd, 2025

II. DEVICE

Proprietary Name:	Quantum Perfusion Centrifugal Blood Pump CP22NG with Integrated Sensors
Common Name:	Centrifugal Blood Pump CP22NG with Integrated Sensors
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class:	II
Product Code:	KFM
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
510(k) Number:	K250326

III. PREDICATE DEVICES

Proprietary Name:	Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors
Common Name:	Centrifugal Blood Pump CP22 with Integrated Sensors
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class:	II
Product Code:	KFM
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
510(k) Number:	K201320

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IV. DEVICE DESCRIPTION

The Quantum Perfusion Centrifugal Blood Pump CP22NG with Integrated Sensors (CP22V-NG) is a standalone, single-use device intended for use in medical procedures requiring extracorporeal circulation. The device is designed to pump blood via centrifugal force through an extracorporeal circuit for periods lasting up to six (6) hours.

The device is non-toxic, non-pyrogenic, EtO-sterilized, and packaged in a single blister. Blood contact surfaces are coated with a stable, biocompatible compound to reduce platelet activation and adhesion while preserving platelet function.

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Perfusion Centrifugal Blood Pump CP22NG with Integrated Sensors indicated for use exclusively with the Quantum Centrifugal Drive is intended to pump the blood through an extracorporeal circuit and to monitor pressure for periods lasting less than 6 hours for the purpose of providing either:

(i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or

(ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Device is intended for adult patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Quantum Perfusion Centrifugal Blood Pump CP22NG with Integrated Sensors (CP22V-NG) has the same intended use, main technological characteristics, and operating principle as the predicate device (K201320). The design modifications characterizing the subject device are improvements to the rotor and housing of the centrifugal blood pump.
In vitro performance tests have been performed to support claimed substantial equivalence and confirm that any differences in the subject device do not raise any new issues related to product safety or effectiveness.

The Quantum Perfusion Centrifugal Blood Pump CP22NG with Integrated Sensors (CP22V-NG) is therefore substantially equivalent to the predicate device per FDA's Guidance Evaluating Substantial Equivalence in Premarket Notifications [510(k)], issued July 28, 2014.

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VII. PERFORMANCE DATA

NON-CLINICAL TESTING

The following activities were performed to demonstrate product safety and effectiveness, considering the proposed change and related impact:

- Biocompatibility testing was performed in accordance with ISO 10993-1:2018 in a previous submission for the Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors (K201320). The modifications to the subject device do not affect the materials, contact type, or contact duration; therefore, the biocompatibility data for the predicate device are valid for the subject device. Refer to K201320 for additional information.
- Validation of the EtO sterilization process was performed in accordance with ISO 11135:2014 and provided in a previous submission for the Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors (K201320). The modifications to the subject device do not affect the materials or sterilization process; therefore, the sterilization data for the predicate device are valid for the subject device. Refer to K201320 for additional information.
- Validation of the product shelf-life was performed and provided in a previous submission for the Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors (K201320). The modifications to the subject device do not affect the device materials; therefore, the shelf-life data for the predicate device are valid for the subject device. Refer to K201320 for additional information.
- Packaging validation was performed in accordance with ISO 11607-1:2019 and provided in a previous submission for the Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors (K201320). The modifications to the subject device do not affect the packaging of the device; therefore the packaging validation for the predicate device are valid for the subject device. Refer to K201320 for additional information.
- Performance testing in accordance with the special controls of 21 CFR 870.4360 was performed with the subject device (CP22V-NG). Such testing included:
    - Operating Parameters,
    - Dynamic Blood Damage,
    - Heat Generation,
    - Air Entrapment,
    - Mechanical Integrity, and
    - Durability/Reliability.

Performance data confirmed that the subject device is equivalent to the predicate device and any differences in the device do not raise new questions of safety or effectiveness.

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Animal Study

No animal studies have been performed to support the substantial equivalence determination of this 510(k).

CLINICAL TESTING

No clinical studies have been performed to support the substantial equivalence determination of this 510(k).

VIII. CONCLUSIONS

Based on the intended use, main technological characteristics, and results of testing, the Quantum Perfusion Centrifugal Blood Pump CP22NG with Integrated Sensors (CP22V-NG) is substantially equivalent to the predicate device (K201320).