July 18, 2024

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

Re: K241206
Trade/Device Name: Quantum Perfusion Hybrid System
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: April 29, 2024
Received: April 30, 2024

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.

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,

Nicole M. Gillette -S

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.

510(k) Number *(if known)*
K241206

Device Name
Quantum Perfusion Hybrid System

Indications for Use *(Describe)*
The Quantum Perfusion Hybrid System is intended to collect, defoam and filter venous and suction blood during cardiopulmonary bypass. The device is intended to be used for periods up to six hours. The 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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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
Fax:	+39 0535 1803051
Date Summary Prepared:	April 29, 2024

II. DEVICE

Proprietary Name:	Quantum Perfusion Hybrid System
Common Name:	Hybrid System
Classification Name:	Reservoir, Blood, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DTN
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)

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III. PREDICATE DEVICES AND REFERENCE DEVICES

Predicate Device

Proprietary Name:	INSPIRE 8F DUAL hollow Fiber Oxygenator with Integrated arterial filter and hardshell venous/cardiotomy reservoir
Registered Establishment Name:	Sorin Group Italia S.r.l.
Classification Name:	Cardiopulmonary Bypass Oxygenator, Reservoir, Blood, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DTN,DTZ
510(k) Number:	K122844

Reference Device

Proprietary Name:	Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface
Registered Establishment Name:	Medtronic Inc.
Classification Name:	Cardiopulmonary bypass Oxygenator
Regulatory Class:	II
Product Code:	DTZ
510 (k) Number:	K183490

IV. DEVICE DESCRIPTION

The *Quantum Perfusion Hybrid System* is a system, including a blood reservoir consisting of an hardshell and softshell reservoir.
The combination of defoaming bodies and filtering media of venous/vent and cardiotomy side allows both the filtration of debris and the retention of air bubbles.
Product configuration includes, together with the Hybrid System, dedicated spare parts:

- an adapter 1/2" – 3/8";
- a spare cap set;

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- a blood sampling set.

The device is intended to be used for periods up to six hours.
The *Quantum Perfusion Hybrid System* is a sterile device with non-pyrogenic fluid pathways, sterilized by ethylene oxide, conceived for single use only and is not to be re-sterilized by the user; the device has a declared shelf life of 2 years.

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Perfusion Hybrid System is intended to collect, defoam and filter venous and suction blood during cardiopulmonary bypass. The device is intended to be used for periods up to six hours. The device is intended for adult patients.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device	Proposed Device – Quantum Perfusion Hybrid System	Predicate Device – INSPIRE 8F DUAL hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir	Reference Device – Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface
Name	Quantum Perfusion Hybrid System	INSPIRE 8F DUAL hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir	Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface
510(k) Number	To be assigned	K122844	K183490
Device description	The Quantum Perfusion Hybrid System (HR04V-A0) mainly consists of two separate chambers: the first chamber collects and filters the non-activated blood coming from patient's vein and the intracardiac suction; The second chamber collects and filters the activated blood coming from the operating field through thoracic and general suction (cardiotomy line). The device can also be used post-operatively for chest drainage.	The INSPIRE 8F DUAL is a high efficiency microporous hollow fiber membrane oxygenator integrated with an arterial filter and a heat exchanger (INSPIRE 8F M) and connected to a hardshell venous/cardiotomy reservoir (INSPIRE HVR DUAL). A molded filling joint connects the oxygenator to the reservoir. The device can be operated at flow rates up to 8 liters per minute (l/min). The hollow fiber membrane oxygenator provides oxygenation and	The Affinity Fusion Oxygenator with Integrated Arterial Filter (OXY) and Balance Biosurface is a single use, microporous, hollow-fiber, gas-exchange device with plasma-resistant fiber and integrated heat exchanger and filter. The OXY is bonded on its primary blood contacting surfaces with a nonleaching biocompatible surface to reduce platelet activation and adhesion and preserve platelet function.

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Device	Proposed Device – Quantum Perfusion Hybrid System	Predicate Device – INSPIRE 8F DUAL hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir	Reference Device – Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface
	The Quantum Perfusion Hybrid Systemr must be used during cardiac surgical procedures requiring cardiopulmonary bypass for a maximum duration of 6 hours and can be operated up to 8 liters per minute (l/min).	carbon dioxide removal from venous blood or suction blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The integrated arterial filter provides additional protection against air and solid emboli and the integrated hardshell reservoir collects, defoams, filters venous and suction blood, and can be used post-operatively for chest drainage.	The Affinity Cardiotomy/Venous Reservoir (CVR) with Balance Biosurface is a single-use device designed to collect and store blood during extracorporeal circulation. Cardiotomy blood is collected, filtered, and defoamed before mixing with the filtered venous blood. With the exception of the filter, the CVR is bonded on its primary venous blood contacting surfaces with a nonleaching biocompatible surface to reduce platelet activation and adhesion and preserve platelet function.
Regulation #	870.4400	870.4350 (oxygenator) 870.4400 (reservoir)	870.4350 (oxygenator) (Please note that some variants included in K183490 present as additional component a reservoir, for which 870.4400 is applicable)
Regulation Name	Reservoir, Blood, Cardiopulmonary Bypass	Cardiopulmonary Bypass Oxygenator Reservoir, Blood, Cardiopulmonary Bypass	Cardiopulmonary Bypass Oxygenator (Please note that some variants included in K183490 present as additional component a reservoir).

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Device	Proposed Device – Quantum Perfusion Hybrid System	Predicate Device – INSPIRE 8F DUAL hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir	Reference Device – Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface
Product Code	DTN	DTZ (oxygenator), DTN (reservoir)	DTZ (oxygenator) (Please note that some variants included in K183490 present as additional component a reservoir, for which DTN product code is applicable)
Classification	II	II	II
Indication for Use	The Quantum Perfusion Hybrid System is intended to collect, defoam and filter venous and suction blood during cardiopulmonary bypass. The device is intended to be used for periods up to six hours. The device is intended for adult patients.	INSPIRE HVR DUAL Hardshell Venous/Cardiotomy Reservoir is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVIR DUAL can be used post-operatively for chest drainage. INSPIRE HVIR DUAL is intended to be used for 6 hours or less.	The Affinity Fusion™ Oxygenator with Integrated Arterial Filter with Balance™ Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration. The Affinity Fusion™ Oxygenator with Integrated Arterial Filter with Balance™ Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to 6 hours during CPB surgery. The Affinity Fusion™ Cardiotomy/Venous Reservoir with

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Device	Proposed Device – Quantum Perfusion Hybrid System	Predicate Device – INSPIRE 8F DUAL hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir	Reference Device – Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface
			Balance™ Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum-assisted venous drainage (VAVD) procedures. The Affinity Fusion™ Cardiotomy/Venous Reservoir with Balance™ Biosurface is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement.
Target population	Adult	Adult and small adult	Adult
Main contacting material	Coating: Phosphorylcholine Filtering media: Polyester (PET) Defoaming body: Polyurethane (PU) Housing: Copolyester	Coating: Phosphorylcholine Filtering media: Polyester (PET) Defoaming body: Polyurethane (PU) Housing: Polycarbonate (PC)	Coating: Hydrophilic biosurface without heparin Filtering media: Information on material N.A.

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Device	Proposed Device – Quantum Perfusion Hybrid System	Predicate Device – INSPIRE 8F DUAL hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir	Reference Device – Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface
			Defoaming body: Polyurethane (PU) Housing: Copolyester (Tritan)
Overall volume capacity [ml]	4300	4500	4500
Min operating level [ml]	150	150	200
Max venous blood flow rate [l/min]	8	8	7
Min venous blood flow rate [l/min]	1	2 0.5 (up to 2h max duration time)[1]	1
Cardiotomy capacity [ml]	1100	1300	NA
Venous section filtration porosity [µm]	40	41	105
Suitable for VAVD	Yes	Yes	Yes
Venous Blood Connector Type	Inlet: 1/2” (12,7mm) Outlet: 3/8” (9.525mm)	Inlet: 1/2” (12,7mm) Outlet: 3/8” (9.525mm)	Inlet: 1/2" with 3/8" adapter Outlet: 3/8"
Single-use	Yes	Yes	Yes
Sterile Condition	Sterile	Sterile	Sterile

[1] According to manufacturer’s IFU.

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Based on the indications for use, main technological characteristics and results of non-clinical testing, subject device has been demonstrated to be appropriate for its intended use and is considered substantially equivalent to legally marketed predicate and reference devices (K122844 and K183490 respectively) according to FDA's Guidance "Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," issued July 28, 2014.

Furthermore, *in-vitro* performance tests have been performed to demonstrate that the proposed device does not raise any new issues in terms of product's safety or effectiveness as compared to predicate and reference devices.

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

The following non-clinical testing was performed to support the substantial equivalence to predicate devices. These testing included biocompatibility evaluation, mechanical and performance verification, labeling and Instructions for Use (IFU), and verification and validation tests. All testing passed by meeting the established requirements set for the use of the devices.
The following areas have been tested and/or evaluated:

- Performance tests, taking into account:
    - ISO 15674:2016+A1: 2020 Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags;
    - Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA, dated November 29, 2000.

    Tests are mainly related to:
        - Device pressure drop;
        - Temperature Probe Verification;
        - Mechanical Resistance of Connectors;
        - Static Integrity of The Device;
        - Coating Coverage and Durability;
        - Mechanical Blood Cell Damage;
        - Air Handling, Clots Inspection and Defoaming Efficiency;

- Static and Dynamic Priming Volume;
- Breakthrough Time and Volume;
- Filtration Efficiency.

- Evaluation of product shelf life;
- Validation of the EtO Sterilization process, according to ISO 11135 [Recognition Nr.: 14-529],
- Packaging Validation tests, according to ISO 11607-1:2019 [Recognition Nr. 14-530],
- Biocompatibility of the finished product, according to 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".

Animal Study

No animal studies have been performed except for mandatory biocompatibility tests 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".

Clinical Testing

No clinical data have been included in the current 510(k) submission to support substantial equivalence to legally marketed predicate and reference devices.

VIII. CONCLUSIONS

Based on the indications for use, main technological characteristics and results of non-clinical testing, the subject device has been demonstrated to be appropriate for its intended use and considered substantially equivalent to predicate and reference devices (K122844 and K183490 respectively).