September 12, 2024

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

Re: K231982
Trade/Device Name: Quantum Perfusion Blood Oxygenator VT75-E1, Quantum Perfusion Blood Oxygenator VT75-E2

Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: August 7, 2024
Received: August 7, 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.

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-

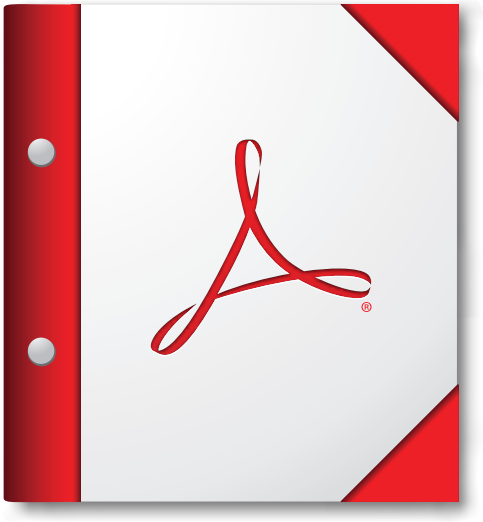
assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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



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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.
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e-mail:	raffaella.tommasini@spectrummedical.com
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Date Summary Prepared:	December 22th, 2023

II. DEVICE

Proprietary Name:	Quantum Perfusion Blood Oxygenator VT75-E1 Quantum Perfusion Blood Oxygenator VT75-E2
Common Name:	Oxygenator
Classification Name:	Oxygenator, Cardiopulmonary Bypass
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)

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III. PREDICATE AND REFERENCE DEVICES

Predicate Device:

Proprietary Name:	Medos Hilite Pediatric Oxygenator 2400 LT
Registered Establishment Name:	GISH BIOMEDICAL INC
Regulation Number:	870.4350
Common Name:	Oxygenator
Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulatory Class:	II
Product Code:	DTZ
510(k) Number:	K090450

Reference Device:

Proprietary Name:	Quantum Perfusion Blood Oxygenators ECC
Registered Establishment Name:	Spectrum Medical S.r.l.
Regulation Number:	870.4350
Common Name:	Oxygenator
Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulatory Class:	II
Product Code:	DTZ
510(k) Number:	K203424

IV. DEVICE DESCRIPTION

The Quantum Perfusion Blood Oxygenator (acronym VT-E) diffusion membrane device is designed to oxygenate blood and remove carbon dioxide from venous blood during cardiac surgical procedures requiring cardiopulmonary bypass for a maximum duration of 6 hours.

Blood enters the oxygenator through the blood inlet connector, flows through a blood chamber, touching the outer surface of hollow fibers membrane; while the sweep gas flows into the hollow fiber membrane. The hollow fibers are made of Polymethylpentene (PMP). In this chamber, carbon dioxide moves from the blood to

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the gas compartment, while oxygen enters into the red blood cells. Then, blood exits the oxygenator with the desired level of oxygen content and saturation, and carbon dioxide content. Sweep gas composition and flow rate are used to control saturation, and oxygen and carbon dioxide content of blood at the outlet of the oxygenator.

The device is non-toxic, non-pyrogenic, sterilized by ethylene oxide and packaged in a single box.

All the device surfaces in contact with blood are treated with a phosphorylcholine-based biocompatible coating.

V. INTENDED USE / INDICATIONS FOR USE

VT75-E1

Quantum Perfusion Blood Oxygenator is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure and temperature during the procedure. The device is limited to 6 hours of use.

Device is intended for Paediatric patients with a Body Surface Area (BSA) ranging from 0.6 m^2 to 1 m^2.

VT75-E2

Quantum Perfusion Blood Oxygenator is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure during the procedure. The device is limited to 6 hours of use.

Device is intended for Paediatric patients with a Body Surface Area (BSA) ranging from 0.6 m^2 to 1 m^2.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

Device	Proposed Device – Quantum Perfusion Blood Oxygenator Spectrum Medical S.r.l.	Predicate Device – Medos Hilite Pediatric Oxygenator 2400 LT GISH BIOMEDICAL INC	Reference Device - Quantum Perfusion Blood Oxygenator ECC Spectrum Medical S.r.l.
Name	Quantum Perfusion Blood Oxygenator VT75-E1 Quantum Perfusion Blood Oxygenator VT75-E2	Medos Hilite Pediatric Oxygenator 2400 LT	Quantum Perfusion Blood Oxygenator ECC VT160-E1 Quantum Perfusion Blood Oxygenator ECC VT160-E2 Quantum Perfusion Blood Oxygenator ECC VT200-E1 Quantum Perfusion Blood Oxygenator ECC VT200-E2
510(k) Number	K231982	K090450	K203424
Device description	The Quantum Perfusion Blood Oxygenator (acronym VT-E) diffusion membrane device is designed to oxygenate blood and remove carbon dioxide from venous blood during cardiac surgical procedures requiring cardiopulmonary bypass for a maximum duration of 6 hours.	The MEDOS HILITE 2400 LT Hollow Fiber Oxygenators consist of a hollow fiber membrane oxygenator and extracorporeal heat exchanger. The MEDOS HILITE 2400 LT hollow fibre membrane consists of a Polymethylpentene gas plasma tight mat. The unique mat design increases the interaction between blood and gas,	The Quantum Perfusion Blood Oxygenator ECC (acronym VT-E) diffusion membrane device is designed to oxygenate blood and remove carbon dioxide

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Device	Proposed Device – Quantum Perfusion Blood Oxygenator Spectrum Medical S.r.l.	Predicate Device – Medos Hilite Pediatric Oxygenator 2400 LT GISH BIOMEDICAL INC	Reference Device - Quantum Perfusion Blood Oxygenator ECC Spectrum Medical S.r.l.
	Blood enters the oxygenator through the blood inlet connector, flows through a blood chamber, touching the outer surface of hollow fibres membrane; while the sweep gas flows into the hollow fibre membrane. The hollow fibres are made of Polymethylpentene (PMP). In this chamber, carbon dioxide moves from the blood to the gas compartment, while oxygen enters into the red blood cells. Then, blood exits the oxygenator with the desired level of oxygen content and saturation, and carbon dioxide content. Sweep gas composition and flow rate are used to control saturation, and oxygen and carbon dioxide content of blood at the outlet of the oxygenator. The device is non-toxic, non-pyrogenic, sterilized by ethylene oxide and packaged in a single box. All the device surfaces in contact with blood are treated with a phosphorylcholine-based biocompatible coating.	creating a highly efficient blood oxygenator. The heat exchanger consists of a polyester non-porous hollow fiber configured heat exchanger as the primary element to affect heat exchange. This element is encased by a polycarbonate housing, which directs the blood around the outside of the fibres while water flow through the inner lumen of the fibres and therefore effects heat exchange while minimizing priming volume.	from venous blood during cardiac surgical procedures requiring cardiopulmonary bypass for a maximum duration of 6 hours. Blood enters the oxygenator through the blood inlet connector, flows through a blood chamber, touching the outer surface of hollow fibres membrane; while the sweep gas flows into the hollow fibre membrane. The hollow fibres are made of Polymethylpentene (PMP). In this chamber, carbon dioxide moves from the blood to the

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Device	Proposed Device – Quantum Perfusion Blood Oxygenator Spectrum Medical S.r.l.	Predicate Device – Medos Hilite Pediatric Oxygenator 2400 LT GISH BIOMEDICAL INC	Reference Device - Quantum Perfusion Blood Oxygenator ECC Spectrum Medical S.r.l.
			gas compartment, while oxygen enters into the red blood cells. Then, blood exits the oxygenator with the desired level of oxygen content and saturation, and carbon dioxide content. Sweep gas composition and flow rate are used to control saturation, and oxygen and carbon dioxide content of blood at the outlet of the oxygenator. The device is non-toxic, non-pyrogenic, sterilized by ethylene oxide and packaged in a single box. All the device surfaces in

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Device	Proposed Device – Quantum Perfusion Blood Oxygenator Spectrum Medical S.r.l.	Predicate Device – Medos Hilite Pediatric Oxygenator 2400 LT GISH BIOMEDICAL INC	Reference Device - Quantum Perfusion Blood Oxygenator ECC Spectrum Medical S.r.l.
			contact with blood are treated with a phosphorylcholine-based biocompatible coating.
Regulation #	870.4350	870.4350	870.4350
Regulation Name	Cardiopulmonary Bypass Oxygenator	Cardiopulmonary Bypass Oxygenator	Cardiopulmonary Bypass Oxygenator
Product Code	DTZ	DTZ	DTZ
Classification	II	II	II
Indication for Use	VT75-E1 Quantum Perfusion Blood Oxygenator VT75-E1 is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure and temperature during the procedure. The device is limited to 6 hours to use. VT75-E2 Quantum Perfusion Blood Oxygenator VT75-E2 is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring	The hilite 2400 LT is a hollow fibre membrane oxygenator is indicated for use in procedures requiring the extracorporeal oxygenation of and carbon dioxide removal from human blood. The 2400 LT is a paediatric oxygenators intended for use at blood flow rates of 0.5 to 2.4 litres per minute for periods of up to six hours.	VT200-E1 and VT160-E1 Quantum Perfusion Blood Oxygenator ECC (VT-E1) is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure

Device	Proposed Device – Quantum Perfusion Blood Oxygenator Spectrum Medical S.r.l.	Predicate Device – Medos Hilite Pediatric Oxygenator 2400 LT GISH BIOMEDICAL INC	Reference Device - Quantum Perfusion Blood Oxygenator ECC Spectrum Medical S.r.l.
	cardiopulmonary bypass and to measure blood pressure during the procedure. The device is limited to 6 hours of use.		blood pressure and temperature during the procedure. The device is limited to 6 hours to use. VT200-E2 and VT160-E2 Quantum Perfusion Blood Oxygenator ECC (VT-E2) is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure during the procedure. The device is limited to 6 hours of use.
Target population	Paediatric ($0.6\ m^2 < BSA < 1\ m^2$)	Paediatric	Adult

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Device	Proposed Device – Quantum Perfusion Blood Oxygenator Spectrum Medical S.r.l.	Predicate Device – Medos Hilite Pediatric Oxygenator 2400 LT GISH BIOMEDICAL INC	Reference Device - Quantum Perfusion Blood Oxygenator ECC Spectrum Medical S.r.l.
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	Fiber: Polymethylpentene	Fiber: Polymethylpentene	Fiber: Polymethylpentene
Sensor Operating Pressure Range	0 to 800 mmHg	N/A	0 to 800 mmHg
Sensor Sensitivity	5µV/V/mmHg ± 1%	N/A	5µV/V/mmHg ± 1%
Sensor Accuracy	0 to 50 mmHg: ±1 mmHg + 1% of reading	N/A	0 to 50 mmHg: ±1 mmHg + 1% of reading
	50 to 800 mmHg: ±1 mmHg + 3% of reading		50 to 800 mmHg: ±1 mmHg + 3% of reading
Sensor Overpressure Protection	-400 to + 6464 mmHg	N/A	-400 to + 6464 mmHg
Blood side Connector Type	1/4" (9.525mm)	1/4" (9.525mm)	3/8" (9.525mm)
Blood flow range [l/min]	0.5 - 2.4	0.5 – 2.4	0.5 - 5
Max pressure drop @ max flow rate [mmHg]	80	150	80

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Device	Proposed Device – Quantum Perfusion Blood Oxygenator Spectrum Medical S.r.l.	Predicate Device – Medos Hilite Pediatric Oxygenator 2400 LT GISH BIOMEDICAL INC	Reference Device - Quantum Perfusion Blood Oxygenator ECC Spectrum Medical S.r.l.
Exchange surface [m^2]	0.8 ±0.02 m^2	0.65 m^2	1.5±0.05 m^2
Priming Volume [ml]	75 ± 5	95	145 ± 10 ml
O2 Gas Transfer [mlO_2/min] @ max flow rate (QBlood:Qgas=1:1)	≥120	≥120	≥250
CO2 Gas Transfer [$mlCO_2$/min] @ max flow rate (QBlood:Qgas=1:1)	≥96	≥96	≥200
Single-use	Yes	Yes	Yes
Sterile Condition	Sterile	Sterile	Sterile
Sterilization Method	EtO sterilization process	EtO sterilization process	EtO sterilization process

Table 1 – Comparative Data with Predicate and Reference Devices

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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:

- Gas transfer performance;
- Temperature probe and Pressure sensor verification;
- Mechanical Blood Cell Damage;
- Device pressure Drop;
- Mechanical Integrity;
- Mechanical resistance of connectors;
- Coating coverage and durability;
- Air handling.

ANIMAL TESTING

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 Traditional 510(k) submission to support substantial equivalence to legally marketed predicate devices.

VIII. CONCLUSIONS

Based on the indications for use, main technological characteristics and results of non-clinical testing, the Quantum Perfusion Blood Oxygenator devices, VT75-E1 and VT75-E2, have been demonstrated to be appropriate for the intended use and are considered substantially equivalent to predicate device, Medos Hilite Pediatric Oxygenator 2400 LT (K090450) and reference Spectrum Medical S.r.l own marketed Quantum Perfusion Blood Oxygenator ECC devices (K203424).