



May 31, 2024

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

Re: K241248

Trade/Device Name: Quantum Perfusion Dual Lumen Cannula 31F-V1
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: May 3, 2024
Received: May 3, 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,

Eric E. Richardson -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

510(k) Number (if known)

K241248

Device Name

Quantum Perfusion Dual Lumen Cannula 31F-V1

Indications for Use (Describe)

The Quantum Perfusion Dual Lumen Cannula is intended for use as a single cannula for both venous drainage and reinfusion of blood via the internal jugular vein during extracorporeal life support procedures for periods of maximum 6 hours.

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
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Date Summary Prepared: May 03, 2024

II. DEVICE

Proprietary Name: Quantum Perfusion Dual Lumen Cannula 31F-V1
Common Name: Dual Lumen Cannula 31F-V1
Classification Name: Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: II
Product Code: DFW
Panel: Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)

III. PREDICATE DEVICES

<u>Proprietary Name:</u>	Quantum Perfusion Dual Lumen Cannula 31F
<u>Common Name:</u>	Dual Lumen Cannula 31F
<u>Registered Establishment Name:</u>	Spectrum Medical S.r.l
<u>Classification Name:</u>	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
<u>Regulatory Class:</u>	II
<u>Product Code:</u>	DWF
<u>Panel:</u>	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
<u>510(k) Number:</u>	K221353

IV. DEVICE DESCRIPTION

Quantum Perfusion Dual Lumen Cannula product family are single use devices intended to be used in medical procedures providing cardiac and/or respiratory support up to 6 hours. Devices are characterized by two coaxial catheters and are designed to be coupled with an extracorporeal circuit for artificial oxygenation of the blood and carbon dioxide removal.

Devices exploit a single site insertion which reduces the invasiveness of extracorporeal procedures. It can be inserted via a percutaneous approach through the right internal jugular vein. Blood is drained through the lumen of the outer catheter and returned through the lumen of the inner catheter.

Devices feature multiple inflow openings in the outer catheter limiting the circulation of unoxygenated blood.

Devices are non-toxic, non-pyrogenic, sterilized by ethylene oxide and packaged in a double pouch. All the devices' surfaces in contact with blood are coated with a phosphorylcholine-based biocompatible material.

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Perfusion Dual Lumen Cannula is intended for use as a single cannula for both venous drainage and reinfusion of blood via the internal jugular vein during extracorporeal life support procedures for periods of maximum 6 hours.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

One additional device model has been introduced in the Dual Lumen Cannula product family in order to provide to clinicians/users an additional option to perform cardiopulmonary bypass procedures.

New REF code introduced in the portfolio Quantum Perfusion Dual Lumen Cannula product family is aligned with information provided in original submission K221353 in terms of general structure, principles of operation, intended use, manufacturing and sterilization process.

Technical specifications have been verified through testing activities performed according to the same internal applicable standards/protocols of the original cleared devices.

Applicable testing activities demonstrated that the proposed device model does not raise any issues of safety and effectiveness as compared to the currently cleared predicate device.

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

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

- Update of labeling and Instructions for Use (IFU) according to ISO 15223-1:2021 Medical Devices - Symbols to Be Used with Medical Device Labels, Labelling, And Information to Be Supplied - Part 1: General Requirements [Recognition Nr. 5-134];
- Performance tests for new REF codes introduced in the portfolio, according to applicable Recognized Consensus Standard ISO 18193:2021 [Recognition Nr. 3-176].

Animal Study

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

CLINICAL TESTING

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

VIII. CONCLUSIONS

Considering all changes performed on original devices cleared K221353 as described in Section “Device Description” of current submission, it could be stated that devices under evaluation are identical in terms of intended use and applicable medical technique.

Based on the testing activities, technological characteristics and the indications for use, the proposed devices have been demonstrated to be appropriate for their intended use and are considered substantially equivalent to Spectrum Medical s.r.l. own original devices.