November 8, 2021

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

Re: K203067
Trade/Device Name: Quantum Perfusion Single Lumen Cannula 22F, Quantum Perfusion Dual Lumen Cannula 31F, Quantum Perfusion Dual Lumen Cannula 27F, Quantum Perfusion Dual Lumen Cannula 24F
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF,
Dated: October 20, 2021
Received: October 28, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

for Nicole Gillette
Assistant Director
Division of Circulatory Support, Structural, and Vascular Devices
Office of Cardiovasular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203067

Device Name
Quantum Perfusion Single Lumen Cannula 22F

Indications for Use *(Describe)*
The Quantum Perfusion Single Lumen Cannula 22F is designed to drain blood from the patient through 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203067

Device Name
Quantum Perfusion Dual Lumen Cannula 24F

Indications for Use *(Describe)*
The Quantum Perfusion Dual Lumen Cannula 24F 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203067

Device Name
Quantum Perfusion Dual Lumen Cannula 27F

Indications for Use *(Describe)*
The Quantum Perfusion Dual Lumen Cannula 27F 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203067

Device Name
Quantum Perfusion Dual Lumen Cannula 31F

Indications for Use *(Describe)*
The Quantum Perfusion Dual Lumen Cannula 31F 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)

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Section 5.0 510(K) SUMMARY

I. SUBMITTER

Submitter Name:	Qura S.r.l.
Submitter Address:	Via di Mezzo, 23 41037 Mirandola (MO) Italy
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Date Summary Prepared:	October 6, 2020

II. DEVICES

Proprietary Name:	Quantum Perfusion Single Lumen Cannula 22F Quantum Perfusion Dual Lumen Cannula 24F Quantum Perfusion Dual Lumen Cannula 27F Quantum Perfusion Dual Lumen Cannula 31F
Common Name:	Single Lumen Cannula 22F Dual Lumen Cannula 24F Dual Lumen Cannula 27F Dual Lumen Cannula 31F
Classification Name:	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class:	II
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
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 device:

Trade Name:	Bio-Medicus Adult Cannulae and Introducer
Registered Establishment Name:	MEDTRONIC, INC.
Regulation Number:	21 CFR 870.4210
Regulation Name:	Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class:	II
Product Code:	DWF
510(k) Number:	K180453

Reference device:

Trade Name:	PROTEK Duo 31 Fr. Veno-Venous Cannula Set
Registered Establishment Name:	CARDIACASSIST, INC.
Regulation Number:	21 CFR 870.4210
Regulation Name:	Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class:	II
Product Code:	DWF
510(k) Number:	K160257

IV. DEVICE DESCRIPTION

Quantum Perfusion Single Lumen Cannula:

Quantum Perfusion Single Lumen Cannula is a single use device intended to be used in medical procedures providing cardiac and respiratory support up to 6 hours. The device is characterized by a single lumen drainage catheter and is designed to be coupled with an extracorporeal circuit, allowing for blood oxygenation and carbon dioxide removal.

The device exploits a percutaneous insertion procedure, which reduces the invasiveness of extracorporeal procedures. It is intended to be inserted in the right internal jugular vein.

The device features multiple inflow openings, allowing to drain blood from the vena cava., providing drainage during extra-corporeal medical procedures.

The device is non-toxic, non-pyrogenic, sterilized by ethylene oxide and packaged in a double pouch. Blood contact surfaces of the device are coated with a stable biocompatible surface.

Quantum Perfusion Dual Lumen Cannula:

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

The device exploits 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.

The device features multiple inflow openings in the outer catheter limiting the circulation of unoxygenated blood.

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

V. INTENDED USE / INDICATIONS FOR USE

Quantum Perfusion Single Lumen Cannula:

The Quantum Perfusion Single Lumen Cannula is designed to drain blood from the patient through the internal jugular vein during extracorporeal life support procedures for periods of maximum 6 hours.

Quantum Perfusion Dual Lumen Cannulae:

- The Quantum Perfusion Dual Lumen Cannula 24F 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.
- The Quantum Perfusion Dual Lumen Cannula 27F 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.
- The Quantum Perfusion Dual Lumen Cannula 31F 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 AND REFERENCE DEVICES

Quantum Perfusion Single Lumen Cannula and Quantum Perfusion Dual Lumen Cannulae have same intended use, technological characteristics and operating principle as the predicate and reference devices (Bio-Medicus Adult Cannulae and Introducer cleared by K180453 and PROTEK Duo 31 Fr. Veno-Venous Cannula Set cleared by K160257).

In-vitro performance tests have been performed in order to support claimed substantial equivalence determining that proposed devices do not raise any new issues in terms of product's safety or effectiveness if compared to currently cleared predicate and reference products.

Quantum Perfusion Single Lumen Cannula and Quantum Perfusion Dual Lumen Cannulae can be therefore considered as substantially equivalent to predicate and reference devices, according to FDA's Guidance "Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," issued July 28, 2014.

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

In-vitro testing was performed to demonstrate products' substantial equivalence with the predicate and reference devices and also to comply with user needs and safety and effectiveness requirements. Testing supplied in the 510(k) Notification includes biocompatibility evaluation, mechanical and performance verification, labeling and Instructions for Use (IFU), verification and validation tests.

All testing passed by meeting the established requirements set for the use of the devices. The following data were provided:

- Evaluation of devices' performances:
    - Device Pressure Drop;
    - Mechanical Integrity;
    - Kinking resistance;
    - Dynamic Blood Damage;
    - Infusion/drainage recirculation;
    - Air aspiration;
    - Marker radiopacity;
    - Pad printing resistance;

  and mainly performed according to ISO/DIS 18193, ISO 10555-1:2013 + AMD 2017 [Recognition Nr.: 6-408] and ASTM F640-12 [Recognition Nr.: 8-418];
- Evaluation of product shelf life, including product's sterility according to EP/UPS requirements;
- Validation of the EtO Sterilization process, according to ISO 11135:2014 [Recognition Nr.: 14-452],
- Packaging Validation tests according to ISO 11607-1:2019 [Recognition Nr.: 14-530];
- Biocompatibility of the finished product, 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".

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

VIII. CONCLUSIONS

Based on the indications for use, technological characteristics and results of non-clinical testing, Quantum Perfusion Single Lumen Cannula and Quantum Perfusion Dual Lumen Cannulae have been demonstrated to be appropriate for their intended use and are considered substantially equivalent to legally marketed predicate and reference devices, Bio-Medicus Adult Cannulae and Introducer (K180453) and PROTEK Duo 31 Fr. Veno-Venous Cannula Set (K160257).