August 18, 2022

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

Re: K221353
Trade/Device Name: Quantum Perfusion Dual Lumen Cannula 31F-VS, Quantum Perfusion Dual Lumen Cannula 29F, Quantum Perfusion Dual Lumen Cannula 29F-V1, Quantum Perfusion Dual Lumen Cannula 27-VS, Quantum Perfusion Dual Lumen Cannula 27-V1, Quantum Perfusion Dual Lumen Cannula 24F-V1, Quantum Perfusion Dual Lumen Cannula 24F, Quantum Perfusion Dual Lumen Cannula 27F, Quantum Perfusion Dual Lumen Cannula 31F
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: July 19, 2022
Received: July 20, 2022

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221353

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221353

Device Name
Quantum Perfusion Dual Lumen Cannula 24F-V1

Indications for Use *(Describe)*
The Quantum Perfusion Dual Lumen Cannula 24F-V1 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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510(k) Number *(if known)*
K221353

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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510(k) Number *(if known)*
K221353

Device Name
Quantum Perfusion Dual Lumen Cannula 27F-V1

Indications for Use *(Describe)*
The Quantum Perfusion Dual Lumen Cannula 27F-V1 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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510(k) Number *(if known)*
K221353

Device Name
Quantum Perfusion Dual Lumen Cannula 27F-VS

Indications for Use *(Describe)*
The Quantum Perfusion Dual Lumen Cannula 27F-VS 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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510(k) Number *(if known)*
K221353

Device Name
Quantum Perfusion Dual Lumen Cannula 29F

Indications for Use *(Describe)*
The Quantum Perfusion Dual Lumen Cannula 29F 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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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K221353

Device Name
Quantum Perfusion Dual Lumen Cannula 29F-V1

Indications for Use *(Describe)*
The Quantum Perfusion Dual Lumen Cannula 29F-V1 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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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221353

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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See PRA Statement below.

510(k) Number *(if known)*
K221353

Device Name
Quantum Perfusion Dual Lumen Cannula 31F-VS

Indications for Use *(Describe)*
The Quantum Perfusion Dual Lumen Cannula 31F-VS 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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510(K) SUMMARY

I. SUBMITTER

Submitter Name:	Qura S.r.l.
Submitter Address:	Via di Mezzo, 23 41037 Mirandola (MO) Italy
Contact Person:	Raffaella Tommasini, QA&RA Director – Qura s.r.l.
Phone:	+39 0535 1803050
e-mail:	raffaella.tommasini@quramed.com
Fax:	+39 0535 1803051
Date Summary Prepared:	May 9th, 2022

II. DEVICE

Proprietary Name:	Quantum Perfusion Dual Lumen Cannula 31F Quantum Perfusion Dual Lumen Cannula 27F Quantum Perfusion Dual Lumen Cannula 24F Quantum Perfusion Dual Lumen Cannula 29F Quantum Perfusion Dual Lumen Cannula 24F-V1 Quantum Perfusion Dual Lumen Cannula 27F-V1 Quantum Perfusion Dual Lumen Cannula 29F-V1 Quantum Perfusion Dual Lumen Cannula 27F-VS Quantum Perfusion Dual Lumen Cannula 31F-VS
Common Name:	Dual Lumen Cannulae
Classification Name:	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DWF
Regulation Number:	21 CFR 870.4210
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)

III. PREDICATE DEVICES

Proprietary Name:	Quantum Perfusion Dual Lumen Cannula 31F Quantum Perfusion Dual Lumen Cannula 27F Quantum Perfusion Dual Lumen Cannula 24F
Common Name:	Dual Lumen Cannulae
Classification Name:	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DWF
Regulation Number:	21 CFR 870.4210
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
510(k) Number:	K203067

IV. DEVICE DESCRIPTION

All medical devices pertaining to 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

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

The present 510(k) is related to the following modifications to Qura's own legally approved predicate products (Quantum Perfusion Dual Lumen Cannulae product family, cleared by K203067):

- Inclusion of new REF Codes in the product family;
- Introduction of a new warning in Instruction for Use to avoid the insertion of the cannula beyond the last depth marker.

The additional variants with different lengths have been introduced in order to provide to clinicians/users additional options as far as patient sizes are concerned. REF codes introduced in the portfolio are aligned with information provided in original submission K203067 in terms of general structure and materials (including packaging), principle of operation, intended use, manufacturing and sterilization processes.

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

The new warning has been introduced in order to mitigate the risk of inserting the cannula too deeply. The portion of the cannula beyond the last depth marker is less flexible than the rest of the cannula and can therefore be subjected to undesirable curve at the insertion point, which can ultimately lead to device damage.

Thus, the devices have the same intended use, principle of operation, and technological characteristics. Applicable testing has demonstrated that the proposed devices do not raise any new issues of safety and effectiveness as compared to the currently cleared predicate products.

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

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

- Update of labeling and Instructions for Use (IFU) according to ISO 15223-1:2016 Medical Devices - Symbols to Be Used with Medical Device Labels, Labelling, And Information to Be Supplied - Part 1: General Requirements [Recognition Nr. 5-117];
- Performance tests for new REF codes introduced in the portfolio, according to applicable Recognized Consensus Standard ISO 18193:2021 [Recognition Nr. 3-176]:
    - Evaluation of devices' Pressure Drop;

    as per same internal applicable standards/protocols applied for predicate devices (K203067).

    The new codes differ from the original ones only regarding the dimensions (French size and length). The general devices' structure, principle of operation, materials and manufacturing processes are the same for all the sizes and therefore data provided in original submission should be considered as still valid and only performance have been verified as affected by the changes.

Animal Study

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

CLINICAL TESTING

No clinical data have been included in the current 510(k) submission.

VIII. CONCLUSIONS

Considering changes performed on original devices cleared by K203067, the 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 Qura's own original devices.