June 30, 2021

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

Re: K203057
Trade/Device Name: Quantum Perfusion Arterial Cannula Graft
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: June 1, 2021
Received: June 3, 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
Acting 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)*
K203057

Device Name
Quantum Perfusion Arterial Cannula Graft

Indications for Use *(Describe)*
The Quantum Perfusion Arterial Cannula Graft is designed to infuse blood to the patient through an arterial vessel during cardiopulmonary bypass procedures for periods of maximum 6 hours. The device is equipped with an additional valved access which allows accessing arterial circulation.

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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Section 5.0 510(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.
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Fax:	+39 0535 1803051
Date Summary Prepared:	June 1, 2021

II. DEVICE

Proprietary Name:	Quantum Perfusion Arterial Cannula Graft
Common Name:	Arterial Cannula Graft
Classification Name:	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class:	II
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 DEVICE

Trade Name:	VASCUTEK CANNULA GRAFT
Registered Establishment Name:	VASCUTEK LTD.
Classification Name:	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DWF
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
510(k) Clearance:	K081560

IV. DEVICE DESCRIPTION

The Quantum Perfusion Arterial Cannula Graft is a standalone single use device intended to be used in medical procedures requiring extracorporeal life support. It is designed to infuse blood coming from extracorporeal circuit into the patient's vascular district while being sutured to an arterial vessel.

The device also consists of a 3/8" barbed connection with a side branch containing a hemostatic valve. Due to this valve, the Quantum Perfusion Arterial Cannula Graft can also act as an additional access for interventional catheterization. This feature allows the clinician to perform a single site access during medical procedures, avoiding multiple site access and thus reducing invasiveness.

The application duration of the Quantum Perfusion Arterial Cannula Graft is 6 hours.

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

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Perfusion Arterial Cannula Graft is designed to infuse blood to the patient through an arterial vessel during cardiopulmonary bypass procedures for periods of maximum 6 hours. The device is equipped with an additional valved access which allows accessing arterial circulation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Quantum Perfusion Arterial Cannula Graft has the same intended use, technological characteristics and operating principle as the predicate device (VASCUTEK CANNULA GRAFT, K081560).

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 products.

Quantum Perfusion Arterial Cannula Graft can be therefore considered as substantially equivalent to predicate device, 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 product substantial equivalence with the predicate device 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 Quantum Perfusion Arterial Cannula Graft. The following data were provided:

- Evaluation of devices' performances:
    - Device pressure drop;
    - Valve backflow and leakage;
    - Graft Water Entry Pressure;
    - Suture retention strength;
    - Dynamic blood damage;
    - Kinking resistance;
    - Mechanical integrity;

    and mainly performed according to ISO/DIS 18193, ISO 7198:2016 [Recognition Nr.: 3-144] and ISO 10555-1:2013 + AMD 2017 [Recognition Nr.: 6-408];
- 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 device.

VIII. CONCLUSIONS

Based on the indications for use, technological characteristics and results of non-clinical testing, the Quantum Perfusion Arterial Cannula Graft has been demonstrated to be appropriate for its intended use and is considered substantially equivalent to claimed predicate VASCUTEK CANNULA GRAFT, cleared by K081560.