May 20, 2022

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

Re: K213540
Trade/Device Name: Quantum SuperPAC Tubing Set, Quantum SuperPAC Cardioplegia Set
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: April 20, 2022
Received: April 22, 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)*
K213540

Device Name
Quantum SuperPAC Tubing Set

Indications for Use *(Describe)*
Quantum SuperPAC Tubing Set is a set of tubing intended for use during cardiopulmonary bypass for a duration up to 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K213540

Device Name
Quantum SuperPAC Cardioplegia Set

Indications for Use *(Describe)*
Quantum SuperPAC Cardioplegia Set is a tubing set used for the infusion of cardioplegia solutions and physiological fluids during cardiac surgery procedures on the heart and great vessels for up to six 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:	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:	April 20th, 2022

II. DEVICES

Proprietary Name:	Quantum SuperPAC Tubing set Quantum SuperPAC Cardioplegia set
Common Name:	Tubing set Cardioplegia set
Classification Name:	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DWF
Panel:	Cardiovascular Medical Specialty 74 - 21 CFR Part 870 Office of Product Evaluation and Quality / Office of Health Technology 2 (OHT2 Cardiovascular Devices) / Division of Health Technology 2B (Circulatory Support, Structural and Vascular Devices)

III. PREDICATE AND REFERENCE DEVICES

Predicate device:

Trade Name:	Tubing Pack
Registered Establishment Name:	Medtronic, Inc.
Regulation Number:	870.4210
Regulation Name:	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DWF
510(k) Number	K171979

Reference devices:

For Quantum SuperPAC Tubing set:

Trade Name:	COBE SMARXT TUBING AND CONNECTORS
Registered Establishment Name:	COBE CARDIOVASCULAR, INC
Regulation Number:	870.4390
Regulation Name:	Tubing, Pump, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DWE
510(k) Number	K981613

For Quantum SuperPAC Cardioplegia set:

Trade Name:	MYOtherm XP Cardioplegia Delivery System With Cortiva BioActive Surface, MYOtherm XP Cardioplegia Delivery System With Cortiva BioActive Surface (Bridge System)
Registered Establishment Name:	Medtronic, Inc
Regulation Number:	870.4240
Regulation Name:	Cardiopulmonary Bypass Heat Exchanger
Regulatory Class:	II
Product Code:	DTR
510(k) Number	K162774

IV. DEVICE DESCRIPTION

Quantum SuperPAC Tubing set devices are designed to connect different devices that are not provided in the Quantum SuperPAC tubing set such as oxygenators, pumps, reservoirs, filters, and other cardiopulmonary bypass components into circuits used in surgical procedures requiring extracorporeal support, for a maximum duration of 6 hours.

Quantum SuperPAC Cardioplegia set devices are designed to connect different devices that are not provided in the Quantum SuperPAC tubing set for the infusion of cardioplegia solutions and physiological fluids during cardiac surgery procedures on the heart and great vessels for up to six hours.

Quantum SuperPAC devices (all variants) are non-toxic, non-pyrogenic, and sterilized by ethylene oxide. Devices are intended for single use only and are not to be resterilized by the user.

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

Quantum SuperPAC devices (all variants) are mainly constituted of polyvinyl chloride (PVC) DOP free tubing and additional components composing the set; different variants are available, varying for tubing dimension and set configuration in order to address customer and surgical procedure specifications.

V. INTENDED USE / INDICATIONS FOR USE

- Quantum SuperPAC Tubing set:

Quantum SuperPAC tubing set is a set of tubing intended for use during cardiopulmonary bypass for a duration up to 6 hours.

- Quantum SuperPAC Cardioplegia set:

Quantum SuperPAC Cardioplegia Set is a tubing set used for the infusion of cardioplegia solutions and physiological fluids during cardiac surgery procedures on the heart and great vessels for up to six hours.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

An extensive and complete comparison between Quantum SuperPAC Tubing set and Quantum SuperPAC Cardioplegia set devices and the predicate/reference devices has been conducted. Devices has the same intended use and operating principle as the predicate and reference devices.

Device	Proposed Devices – Quantum SuperPAC Tubing Set Quantum SuperPAC Cardioplegia set	Predicate Device – Medtronic, Inc. Tubing Pack	Reference Device – Cobe Cardiovascular Inc COBE SMARXT Tubing and Connectors	Reference Device – Medtronic, Inc. MYOtherm XP Cardioplegia Delivery System
Name	Quantum SuperPAC Tubing Set Quantum SuperPAC Cardioplegia Tubing Set	Tubing, Connectors and Accessories	COBE SMARXT Tubing and Connectors	MYOtherm XP Cardioplegia Delivery System With Cortiva BioActive Surface, MYOtherm XP Cardioplegia Delivery System With Cortiva BioActive Surface (Bridge System)
510(k) Number	N.A.	K171979	K981613	K162774
Device description	Quantum SuperPAC Tubing Set is a tubing and components set connecting different medical devices used during the extracorporeal procedure up to six hours. Quantum SuperPAC Cardioplegia Tubing Set is a	Medtronic Tubing Packs consist of coated and uncoated tubing, connectors and various medical devices that are pre-assembled into user-specified extracorporeal cardiopulmonary bypass perfusion circuits. Tubing Packs are intended for use within the	The COBE SMART Tubing and Connectors are used in connecting oxygenators, reservoirs, filters and other cardiopulmonary bypass components into circuits used in surgical procedures requiring extracorporeal support	The MYOtherm XP cardioplegia delivery system with Cortiva bioactive surface is comprised of polycarbonate housing and comes preconnected to tubing and connector components comprised of polycarbonate, polyvinyl chloride and plastisol materials and

Device	Proposed Devices – Quantum SuperPAC Tubing Set Quantum SuperPAC Cardioplegia set	Predicate Device – Medtronic, Inc. Tubing Pack	Reference Device – Cobe Cardiovascular Inc COBE SMARXT Tubing and Connectors	Reference Device – Medtronic, Inc. MYOtherm XP Cardioplegia Delivery System
	tubing and components set used during extracorporeal circulation to infuse cardioplegia/physiologic fluids solution up to six hours.	extracorporeal blood pathway during cardiopulmonary bypass surgical procedures.		provided in Y-type, straight, reducer and tubing configurations.
Regulation #	870.4210	870.4210	870.4390	870.4240
Regulation Name	Cardiopulmonary bypass vascular catheter, cannula, or tubing	Cardiopulmonary bypass vascular catheter, cannula, or tubing	Cardiopulmonary bypass pump tubing	Cardiopulmonary bypass heat exchanger.
Product Code	DWF	DWF	DWE	DTR
Classification	II	II	II	II
Indication for Use	Quantum SuperPAC tubing set is a set of tubing intended for use during extracorporeal circulation for a duration up to 6 hours. Quantum SuperPAC Cardioplegia Set is a tubing set used for the infusion of cardioplegia solutions and physiological fluids during cardiac surgery procedures on the heart and great vessels for up to six hours.	The Medtronic Tubing Pack is indicated for use in the extracorporeal circuit during cardiopulmonary bypass (CPB) surgical procedures.	The COBE SMART Tubing and Connectors are intended to be used in surgical procedures requiring extracorporeal support for periods of up to six hours	The MYOtherm XP with Cortiva bioactive surface is a device intended for the mixing, warming/cooling and delivery of oxygenated blood/cardioplegia solution in a predetermined ratio during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration. Blood/cardioplegia solution is delivered to the patient through the cardioplegia delivery system and appropriate cannula by the operation of a

Device	Proposed Devices – Quantum SuperPAC Tubing Set Quantum SuperPAC Cardioplegia set	Predicate Device – Medtronic, Inc. Tubing Pack	Reference Device – Cobe Cardiovascular Inc COBE SMARXT Tubing and Connectors	Reference Device – Medtronic, Inc. MYOtherm XP Cardioplegia Delivery System
				single occlusive roller pump.
Target population	Patient requiring extracorporeal circulation procedures for period up to 6 hours	Patient requiring CPB procedures for period up to 6 hours	Patient requiring surgical procedures requiring extracorporeal support for periods of up to six hours	Patient requiring cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.
Target User	Perfusionist	Perfusionist	Perfusionist	Perfusionist
Biocompatibility Requirements	In compliance with ISO 10993 series	In compliance with ISO 10993 series	In compliance with ISO 10993 series	In compliance with ISO 10993 series
Main Contacting Materials	DOP-free polyvinyl chloride (PVC) Polycarbonate (PC) Phosphorylcholine coating	DOP-free polyvinyl chloride (PVC) Polycarbonate (PC) Cortiva, Trillium and Balance coating	DOP-free polyvinyl chloride (PVC) Polycarbonate (PC) SMART coating	Polyvinyl chloride (PVC) Polycarbonate (PC) Plastisol materials
Blood side Connection Type	3/8x3/32" 1/2x3/32" 1/4X1/16" 3/16x1/16"	0.085x.062 mm 0.107x.040mm 1/2X1/8" 1/2x3/32" 1/4X1/16" 3/16x1/16" 5/16x3/32"	From 0.075x0.028" to 5/8x1/8"	3/8'' - 3/16"
Single-use	Yes	Yes	Yes	Yes
Sterile Condition	Sterile	Sterile	Sterile	Sterile
Description of the sterilization method	EtO sterilization process	EtO sterilization process	EtO sterilization process	EtO sterilization process

Table 5-1 – Comparative Data

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

The following non-clinical testing was performed to support the substantial equivalence Quantum SuperPAC Tubing set and Quantum SuperPAC Cardioplegia set devices to the legally marketed predicate devices. This testing included biocompatibility evaluation, mechanical and performance verification, labeling and Instructions for Use (IFU), and verification and validation tests.

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

- Performance tests, mainly related to:
    - Operating Parameters,
    - Mechanical Integrity,
    - Device pressure drop,
    - Spallation and Tubing Life,
    - Connection strength,

and mainly performed according to ISO 15676.

- 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.: 14-529],
- Packaging Validation tests, according to ISO 11607-1:2019 [Previous Edition Recognition Nr. 14-454], ASTM F1886/F1886M-16 [Recognition Nr. 14-501], EN 868-5 and ASTM F1929-15 [Recognition Nr. 14-484],
- Biocompatibility of the finished product, according to 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, results of non-clinical testing, and comparison to predicate and reference devices, Quantum SuperPAC Tubing set and Quantum SuperPAC Cardioplegia set devices have been shown to be substantially equivalent to legally marketed predicate and reference devices.