June 2, 2022

Marvao Medical Devices Ltd
Mary Legraw
Regulatory Consultant to Marvao Medical
Avania Ltd
100 Crowley Drive, Suite 216
Marlborough, Massachusetts 01752

Re: K220632
Trade/Device Name: Boss Crossing Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 2, 2022
Received: March 4, 2022

Dear Mary Legraw:

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 and Part 809); 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 Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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)*
K220632

Device Name
Boss Crossing Support Catheter

Indications for Use *(Describe)*
The Boss Crossing Support Catheter (Boss CSC) is indicated to guide and support a guidewire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.

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."

Traditional Premarket Notification Submission
Boss Crossing Support Catheter
Date Prepared: March 2, 2022

Submitter

Name:	Marvao Medical Devices Ltd.
Address:	Unit 1 Galway Business Park, Dangan, Galway H91 A3EF Ireland Chris.davey@marvaomedical.com +353 (0)91-759301
Contact Person:	Mary P. LeGraw Avania 100 Crowley Drive, Suite 216 Marlborough, MA 01752 mary.legraw@avaniaclinical.com Phone: (617) 820-0387

Device

Name of Device:	Boss Crossing Support Catheter
Common Name:	Support Catheter
Classification Name:	Percutaneous Catheter
Regulatory Class:	Class II
Product Code:	DQY
Device Panel:	Division of Cardiovascular Devices

Predicate Device

Primary Predicate Name and 510(k) Number:	Terumo NaviCross Support Catheter K173779 (0.018”)
Reference Device:	Terumo NaviCross Support Catheter K110540 (0.035”)

Device Description

The Boss Crossing Support Catheter (Boss CSC) is intended to guide and support a guidewire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or other diagnostic contrast agents. The proposed device is intended for single use and is provided sterile using Ethylene Oxide gas. The device consists of two low

profile catheters, 2.4F and 3.9F, which are compatible with 0.018” and 0.035” guidewires, respectively. Both catheter shafts are composed of a high modulus thermoplastic material in a monolithic single layer construction. The proximal end of each catheter includes a standard catheter hub with Luer fitting and a strain relief. Like the predicate, Terumo NaviCross Support catheters, the distal end of the Boss CSC catheter is equipped with an RO marker band to enable visibility under fluoroscopy. There is a hydrophilic coating on the distal portion of each catheter shaft to enhance lubricity.

The 2.4Fand 3.9F catheters are packaged together in individual spiral HDPE hoops that are secured to a HDPE card and placed inside a Tyvek Mylar pouch. There are two versions of the device offered:

1. 3.9F/90cm length catheter packaged with a 2.4F/135cm length catheter
2. 3.9F/90cm length catheter packaged with a 2.4F /150cm length catheter

As stated, the 2.4F and 3.9F catheters are packaged together. Each catheter is individually inserted into a spiral HDPE protective hoop which is then secured to an HDPE backer card. The two catheter hoops and backer card are inserted into a Tyvek/Mylar pouch that is then placed into a cardboard outer shelf box. Five (5) individual pouches are then placed in a cardboard shelf box.

Principle of Operation

The subject device and predicate devices share the same principle of operation. The physician first establishes access to the vasculature with an introducer sheath and guidewire using standard endovascular procedures and techniques. Like the Terumo NaviCross Support catheters, the BOSS catheter is advanced over a guidewire toward the target vessel. The BOSS catheter is then used to provide support for the guidewire, as needed, while the physician advances the guidewire deeper into the target vessel. As is the case with Terumo’s NaviCross catheter, the physician can use the BOSS catheter to exchange the guidewire if needed, and the catheter itself can also be exchanged over the guidewire as needed, or the 0.018” wire compatible catheter can be advanced through the 0.035” wire compatible catheter. Like the Terumo NaviCross catheter, the BOSS catheter can also be used for injection of saline or contrast media.

Indications for Use

The Boss Crossing Support Catheter (Boss CSC) is indicated to guide and support a guidewire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.

Substantial Equivalence Summary

The proposed device is substantially equivalent in regard to design and materials to the predicate Terumo NaviCross Support catheters 510(k) K110540 (0.035”) and 510(k) K173799 (0.018”) device.

Performance Testing

Bench testing was completed to assure the device performed as intended in accordance with design and functional specifications. The Boss CSC catheters submitted in this 510(k) have demonstrated similar performance characteristics to the predicate devices. Testing was performed on aged and non-aged Boss CSC catheters. The following performance tests were conducted on these catheters.

- Visual and Dimensional Verification
- Simulated Use
- Kink Resistance
- Catheter Shaft Tensile Strength
- Luer to Shaft Joint Tensile Strength
- Distal Catheter Shaft Tensile Strength
- Luer Hub Physical Performance
- Torque Test
- Leak Test
- Catheter Burst Test
- Flow Rate Test
- Hydrophilic Coating Integrity Test
- Package Integrity Test (Seal Strength, Bubble Leak, Visual and Dimensional)
- Simulated Distribution Test

The performance of the Boss CSC Catheters demonstrates substantial equivalence to the performance of the predicate devices.

Biocompatibility Test Summary

Biocompatibility testing per ISO 10993-1 demonstrates the device is biocompatible. The following testing was performed:

- Cytotoxicity,
- Maximization Sensitization,
- Intracutaneous Reactivity
- Systemic Toxicity
- Pyrogenicity
- ASTM Hemolysis (Direct and Indirect)
- SC5b-9 Complement Activation Assay
- Hemocompatibility

Sterilization and Shelf Life Summary

The Boss CSC catheters are single-use devices sterilized using EO gas. Sterilization is conducted in accordance with ANSI/AAMI/ISO 11135-1, Sterilization of health care products –

Ethylene Oxide-Part 1: Requirements for development, validation and routine control of sterilization process for medical devices. The device is sterilized to a SAL of 10^{-6}.

Accelerated aging testing was performed post device sterilization that supports a shelf life of 12 months from the date of sterilization.

Conclusions

Marvao Medical Devices believes the proposed Boss Crossing Support Catheter is substantially equivalent to the legally marketed predicate devices. The indications for use, methods of operation, design and materials used are either identical or substantially equivalent to existing legally marketed predicate products. In addition, performance testing supports substantial equivalence of the proposed and predicate devices.