February 17, 2022

Cordis Corporation
Vidya Venkataraghavan
Principal Specialist, Regulatory Affairs
14201 N.W. 60th Avenue
Miami Lakes, Florida 33014

Re: K212977
Trade/Device Name: SUPER TORQUE MB Angiographic Catheter with Radiopaque markerbands
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 20, 2021
Received: December 21, 2021

Dear Vidya Venkataraghavan:

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 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)*
K212977

Device Name
SUPER TORQUE® MB Angiographic Catheter

Indications for Use *(Describe)*
Cordis Angiographic Catheters with Marker Bands are designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to selected sites in the vascular system.

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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510(k) Summary

I. SUBMITTER

Applicant:
Cordis US Corp.
14201 North West 60th Avenue
Miami Lakes, Florida 33014 USA
Establishment Registration: 1016427

Contact:
Vidya Venkataraghavan
Cordis US Corp.
Tel: (408) 718-1348
vidya.venkataraghavan@cordis.com

Date Prepared: December 20, 2021

II. DEVICE

Name of Device: **SUPER TORQUE® MB Angiographic Catheter**
Common Name: Angiographic Catheter
Classification Name: Diagnostic Intravascular Catheter (21 CFR 870.1200), Class II
Product Code: DQO

III. PREDICATE DEVICE

SUPER TORQUE® MB Angiographic Catheter with Radiopaque Marker Bands cleared on October 8, 1999 under K992347.

IV. DEVICE DESCRIPTION

The SUPER TORQUE® MB Angiographic Catheter is a thin plastic tube which is inserted into an artery through a small incision in the skin. The catheter is guided to the area being examined, and contrast material is injected through the tube and images are captured using a small dose of ionizing radiation (x-rays).

Each SUPER TORQUE® MB Angiographic Catheter consists of a braided Polyurethane body and a non-braided Polyurethane tip section having multiple, radiopaque marker bands.

It is available in the following configurations:

Catalog Numbers
532598A
532598B
532598C
SRD7040MB

The materials of construction of the SUPER TORQUE® MB Angiographic Catheter are as follows:

Component	Materials	Patient Contact
Catheter Body	Pellethane, Barium Sulphate, Stainless steel wire	Direct
Catheter Tip	Pellethane, Barium Sulphate	Direct
Marker Bands	Gold-alloy marker	Direct
Strain Relief	Combination of various polyurethane grades	Indirect
Hub	Isoplast	Indirect
Coating	51-3 solution	Direct

IV. INDICATIONS FOR USE

Cordis Angiographic Catheters with Marker Bands are designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to selected sites in the vascular system.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed SUPER TORQUE® MB Angiographic Catheter and the predicate device cleared under K992347 are inserted into the artery through a small incision in the skin. Both contain a luer connector, braided catheter body and an atraumatic tip.

The proposed SUPER TORQUE® MB Angiographic Catheter is the same device as that of the currently cleared device with an addition of below labeling contraindication.

'Do not use the SUPER TORQUE MB catheter in procedures where entrapment of the catheter between endovascular devices and the vessel wall may occur, for example endovascular aortic repair (EVAR) procedures.'

VII. PERFORMANCE DATA

Bench Testing

No new testing was required to be conducted due to addition of contraindication in the IFU. However, since the clearance of the original 510(k), minor manufacturing updates were made, additional biocompatibility testing was performed, and additional sterilization facilities were qualified.

The testing previously conducted, and the additional testing provided in this 510(k) confirm that the SUPER TORQUE® MB Angiographic Catheter meets established performance characteristics.

Clinical Studies

No clinical data was required in support of the proposed change to the predicate device cleared under K992347.

VIII. CONCLUSIONS

The information presented in this Premarket Notification demonstrates the following for the SUPER TORQUE® MB Angiographic Catheter:

- SUPER TORQUE® MB Angiographic Catheter has a legally-marketed predicate
- SUPER TORQUE® MB Angiographic Catheter has the same Intended Use as the predicate
- SUPER TORQUE® MB Angiographic Catheter incorporates the same fundamental technology as the predicate
- Accepted scientific methods and international standards were used to evaluate substantial equivalence of the SUPER TORQUE® MB Angiographic Catheter relative to the predicate
- Performance characteristics of the SUPER TORQUE® MB Angiographic Catheter are equivalent to the predicate device.

Based on the intended use, technological characteristics, and safety and performance testing, the SUPER TORQUE® MB Angiographic Catheter has been shown to be appropriate for its intended use and is considered substantially equivalent to the predicate SUPER TORQUE® MB Angiographic Catheter with Radiopaque Marker Bands (K992347).