August 8, 2018

Cordis, a Cardinal Health Company
Ms. Vidya Venkataraghavan
Principal Specialist, Regulatory Affairs
1820 McCarthy Boulevard
Milpitas, California 95035

Re: K181836
Trade/Device Name: 4F Infiniti Angiographic Catheter, 4F & 5F Nylex Angiography Catheters, 4F & 5F Tempo Angiography Catheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: July 9, 2018
Received: July 10, 2018

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
For 2018.08.08 20:57:04 -04'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181836

Device Name
4F Infiniti™ Angiographic Catheter
4F and 5F Nylex™ Angiography Catheters
Tempo™ Angiography Catheter

Indications for Use *(Describe)*
The Cordis 4F Infiniti™ Angiographic Catheters are intended for the delivery of radiopaque contrast medium to selected sites in the vascular system.

Cordis Nylex™ Angiography Catheters are designed to deliver radiopaque contrast medium to selected sites in the vascular system.

Cordis Tempo™ Angiography Catheters are intended for the delivery of radiopaque contrast medium to selected sites in the vasculature.

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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SPECIAL 510(K) PREMARKET NOTIFICATION

4F INFINITI ANGIOGRAPHIC CATHETER
4F & 5F NYLEX ANGIOGRAPHY CATHETERS
4F & 5F TEMPO ANGIOGRAPHY CATHETERS

3. 510(K) SUMMARY

510(K) number: **K181836**

I. SUBMITTER

Cordis Corporation, a Cardinal Health Company
1820, McCarthy Boulevard
Milpitas, CA 95035
Tel: (408) 273-3700

Contact Person: Vidya Venkataraghavan
Tel: (408) 273-3451
Fax: (408) 955-0704

Alternate Contact: Andrew Nguyen
Tel: (408) 273-3445
Fax: (408) 955-0704

Date Prepared: August 7, 2018

II. DEVICE

Name of Device: **4F Infiniti™ Angiographic Catheter**
Common Name: Diagnostic catheter
Classification Name: Diagnostic intravascular catheter (21 CFR §870.1200)
Regulatory Class: Class II
Product Code: DQO

Name of Device: **4F & 5F Nylex™ Angiography Catheters**
Common Name: Diagnostic catheter
Classification Name: Diagnostic intravascular catheter (21 CFR §870.1200)
Regulatory Class: Class II
Product Code: DQO

Name of Device: **4F & 5F Tempo™ Angiography Catheters**
Common Name: Diagnostic catheter
Classification Name: Diagnostic intravascular catheter (21 CFR §870.1200)
Regulatory Class: Class II
Product Code: DQO

III. PREDICATE DEVICE

4F Infiniti™ Angiographic Catheter, K960975 for subject 4F Infiniti™ Angiographic Catheter

4F & 5F Nylex™ Angiography Catheters, K971646 for subject 4F & 5F Nylex™ Angiography Catheters

4F Tempo™ Angiography Catheter, K991673 for subject 4F & 5F Tempo™ Angiography Catheters.

IV. DEVICE DESCRIPTION

The **4F Infiniti™ Angiographic Catheter** is a single-use device designed to deliver radiopaque contrast medium to selected sites in the vascular system. The device combines an atraumatic tip with a braided body. It is compatible with 0.038" guidewire. The Infiniti™ 4F catheter is supplied sterile and is available in various lengths and tip configurations.

The **4F & 5F Tempo™ Angiography Catheters** are single-use devices designed to deliver radiopaque contrast medium to selected sites in the vascular system. The device combines an atraumatic tip with a braided body. It is compatible with 0.038" guidewire. The Tempo™ 4F & 5F catheter is supplied sterile and is available in various lengths and tip configurations.

The **4F & 5F Nylex™ Angiography Catheters** are single-use devices designed to deliver radiopaque contrast medium to selected sites in the vascular system. The device combines an atraumatic tip with a non-braided body. It is compatible with 0.035" guidewire. The Nylex™ 4F & 5F catheter is supplied sterile and is available in various lengths and tip configurations.

V. INDICATIONS FOR USE

The **Cordis 4F Infiniti™ Angiographic Catheters** are intended for the delivery of radiopaque contrast medium to selected sites in the vascular system.

Cordis Nylex™ Angiography Catheters are designed to deliver radiopaque contrast medium to selected sites in the vascular system.

Cordis Tempo™ Angiography Catheters are intended for the delivery of radiopaque contrast medium to selected sites in the vasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed 4F Infiniti™ Angiographic Catheter is identical to the predicate 4F Infiniti™ Angiographic Catheter, proposed 4F & 5F Nylex™ Angiographic Catheters are identical to the predicate 4F & 5F Nylex™ Angiography Catheters and proposed 4F & 5F Tempo™ Angiographic Catheters are identical to the predicate 4F & 5F Tempo™ Angiography Catheters in its basic design, intended use, Indications for Use statement, contraindications, mechanism of action,

operating principle, sterilization method and sterility assurance level (SAL). The proposed catheters vary in the material used for the catheter tip. Rilsan ® 6733 used in the single layer tip with a new compound GPX-64 and replacement of Bismuth Subcarbonate with Bismuth Subcarbonate Blend (a combination of Bismuth Subcarbonate and Zinc Stearate as a processing aid).

In the case of Tempo catheters, the change also extends to the replacement of polyamide resin Rilsan ® 6733 used in inner layer of tri-layer intermediate tip by Pebax 55 and the inclusion of an antioxidant heat and light (H & L) stabilization package in the Tungsten compound used for the tri-layer tip inner layer compound to the predicate device. Rilsan® 6733 is replaced by Pebax 55 in the outer layers of the tri-layer tip along with Bismuth Subcarbonate and Zinc Stearate.

Other dimensional specifications, including the catheter length, tip OD, tip ID and guidewire compatibility are identical to the predicate. Design verification and validation testing demonstrate that the catheter continues to meet all previous performance specifications and that none of the critical clinical performance parameters have changed.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing

Biocompatibility testing was conducted on finished and sterilized Tempo 4F Angiographic Catheter in compliance with ISO 10993-1:2009/Cor 1:2010 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, June 2016. Biocompatibility testing included the following:

- In vitro cytotoxicity – MEM elution
- Sensitization - Guinea pig maximization
- Intracutaneous / irritation reactivity
- Acute system toxicity
- Material mediated pyrogenicity
- Hemocompatibility
    - In vitro hemolysis (Direct & extract)
    - Partial thromboplastin time (PTT)
    - Platelets and leukocyte counts
    - Complement activation (C3a & SC 5b-9)
    - In vivo thrombogenicity

Device Functional Testing

- Pull force intermediate tip-to-distal tip
- Pull force tip-to-body

Sterilization Testing

- Bioburden
- EO residuals
- Bacterial Endotoxin

VIII. CONCLUSIONS

The proposed 4F Infiniti™ Angiographic Catheter, 4F & 5F Nylex™ Angiography Catheters and 4F & 5F Tempo™ Angiography Catheters are the same in basic design and has the identical intended use as the currently marketed predicate.

The modifications made to the polyamide resin Rilsan 6733®, and replacement of Bismuth Subcarbonate does not alter the fundamental scientific technology of the device, the device's operating principles, mechanism of action, the indication for use of the device.

The design modifications were verified and validated through a series of tests ensuring that the proposed catheter meets all the required specifications and that the performance and functionality of the proposed devices are substantially equivalent. The proposed 4F Infiniti™ Angiographic Catheter, 4F & 5F Nylex™ Angiographic Catheters and 4F & 5F Tempo™ Angiographic Catheters continues to meet all previous performance specifications and none of the critical clinical performance parameters have changed. The proposed 4F Infiniti™ Angiographic Catheter, 4F & 5F Nylex™ Angiographic Catheters and 4F & 5F Tempo™ Angiographic Catheters can be used according to its intended use and in an equivalent manner to the predicate device. The proposed 4F Infiniti™ Angiographic Catheter, 4F & 5F Nylex™ Angiographic Catheters and 4F & 5F Tempo™ Angiographic Catheters are substantially equivalent to the predicate.