DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 18, 2016

Lake Region Medical
Mr. Michael Dunning
QA/RA Manager
Parkmore West Business Park
Galway G07001
Ireland

Re: K160643
Trade/Device Name: ENROUTE 0.014" Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 7, 2016
Received: September 9, 2016

Dear Mr. Dunning:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Brian D. Pullin -S

for 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160643

Device Name
ENROUTE 0.014" Guidewire

Indications for Use *(Describe)*
The ENROUTE 0.014" Guidewire is intended for use in the peripheral vasculature.

Contraindications:
ENROUTE 0.014" Guidewire is not intended for use in:
- The cerebral or coronary vasculature
- Patients judged not acceptable for percutaneous intervention

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 – ENROUTE 0.014" Guidewire
K160643 - Traditional 510(k)

Device Name	ENROUTE 0.014" Guidewire	
Submitters name	Brivant Ltd T/A Lake Region Medical International Research & Development Centre, Parkmore West Business Park, Co. Galway, Ireland.	
Application Correspondent	Michael Dunning QA/RA Manager Brivant Ltd T/A Lake Region Medical International Research & Development Centre Tel: +353 91 385391 Fax: +353 91 766598	
Summary Preparation Date	7th September 2016	
Device Name & Classification	Trade Name: Common Name: Classification Name: Device Classification: Product Code:	ENROUTE 0.014" Guidewire Guidewire Catheter, Guidewire Class II, 21 CFR §870.1330 DQX
Intended Use	Intended Use: The ENROUTE 0.014" Guidewire is intended for use in the peripheral vasculature. Contraindications: ENROUTE 0.014" Guidewire is not intended for use in: • The cerebral or coronary vasculature. • Patients judged not acceptable for percutaneous intervention.	
Device Description	The ENROUTE .014" guidewire is a disposable medical device designed for single use only. It consists of a 95cm PTFE coated 0.014" diameter stainless steel core wire, one end of which is reduced in diameter over approximately 9.5cm in a progressive fashion through a centreless grinding operation. The profile of this reduced section affords the product an area of reduced stiffness. The very distal tip section is flattened to further reduce stiffness and enable the tip to be shaped. The distal section is covered with a 5cm platinum tungsten spring coil. This provides for greater visibility on x-ray equipment (radiopacity). A hydrophilic coating is applied to the distal section to enhance lubricity. The product is available in straight configuration	

Predicate Device	**Manufacturer**	**510k**	**Date**
	Brivant Guidewire (Rapidwire Plus variant – previously known as SLK)	K060551	06/07/2006
	Nitrex Nitinol Guidewire	K040345	03/02/2004
Principle of Operation	The ENROUTE 0.014" guidewire is operated manually by a manual process		
Comparison of Technological Characteristics	The key technological and performance similarities examined between the approved devices and the proposed ENROUTE 0.014" Guidewire device are as follows: - Indications for use - The Indications for use for the proposed device is a subset of indications for use of the predicate device as proposed device, ENROUTE 0.014" is for peripheral vasculature only - Contraindications – The contraindications for use are very similar to that of the predicate device Nitrex Nitinol Guidewire. The ENROUTE 0.014" device has an additional contraindication to the predicate Rapidwire Plus against use in the Coronary Vasculature. - Fundamental scientific technology, including design - identical to the predicate devices - Operating principle - identical to the predicate devices - Packaging materials - identical to the predicate device Rapidwire Plus - Sterility assurance level and method of sterilization - identical to the predicate devices - The length of the device is within the length range of the predicate device; Nitrex Nitinol Guidewire - The diameter of the proposed device is within the diameter range of the predicate devices (0.014") - The proposed device and that of the Rapidwire Plus device are identical in that they are constructed with a stainless steel core which is reduced in diameter at the distal end to provide flexibility - The proposed device has equivalent tip stiffness characteristics to that the Rapidwire Plus device - The proposed device has an identical hydrophilic coating to that of the Rapidwire Plus device at the distal tip - All devices have a PTFE coating on the guidewire shaft - The proposed device and that of the Rapidwire Plus device have equivalent torque response properties		

- Compatible with equivalent interventional devices

Performance Testing (non-clinical)

In vitro bench tests were utilized to demonstrate equivalence with reference to the FDAs guidance document "Coronary and Cerebrovascular Guidewire Guidance, Jan 1995".

The following bench tests support the proposed product:

Test	**Leveraged from Predicate 510(k) Data**	**ENROUTE 0.014" 510(k) data**
Tensile Strength	X	
Torque Strength		X
Dimensional measurements	X	X (Overall length)
Torque Response		X
Catheter Compatibility		X
Coating Adherence/Coating Integrity	X	
Particulate Testing	X	
Tip Stiffness/Flexibility	X	
Radiopacity		X
Biocompatibility	X	
Shelf Life	X	

The performance testing assessment supports that the biocompatibility, shelf life, and functional specifications of the proposed ENROUTE 0.014" Guidewire device were met. The ENROUTE 0.014" Guidewire device test data supports the claims of substantial equivalence to the predicate devices.

Biological Safety of the predicate device has been established through biocompatibility testing carried out in compliance with ISO10993-1:2009 and G95-1, FDA General Program Memorandum: Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

Conclusions

Based on safety and performance testing, technological characteristics and the indications for use for the device, the ENROUTE 0.014" Guidewire has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.