DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 17, 2014

Lake Region Medical
Mr. Kenneth Walsh
Quality Manager
Parkmore West Business Park
Galway, Ireland

Re: K140536
Trade/Device Name: Hi Torque Connect Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: October 28, 2014
Received: November 3, 2014

Dear Mr. Walsh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to

proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA.

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" (21CFR 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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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 on last page.

510(k) Number *(if known)*
K140536

Device Name
Hi Torque Connect Guidewire

Indications for Use *(Describe)*
Hi-Torque guide wires are indicated to facilitate the placement of percutaneous devices during Percutaneous Transluminal Angioplasty (PTA) in peripheral arteries such as femoral, popliteal and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Lake Region Medical®

Product: Hi Torque Connect Guidewire
Submission Type: Traditional 510(k)
Submission Date: March 28, 2014

510(k) Summary

Device Name	Hi Torque Connect Guidewire
Submitters name	Lake Region Medical Limited, Butlersland, New Ross, Co. Wexford, Ireland.
Application Correspondent	Kenneth Walsh Regulatory Affairs Group Leader Lake Region Medical Limited Tel: +353 91 385037 Fax: +353 91 766598
Summary Preparation Date	28th March 2014
Device Name & Classification	Trade Name: Hi Torque Connect Guidewire Common Name: Guidewire Classification Name: Catheter, Guidewire Device Classification: Class II, 21 CFR §870.1330 Product Code: DQX
Intended Use	Intended Use: Hi-Torque guide wires are indicated to facilitate the placement of percutaneous devices during Percutaneous Transluminal Angioplasty (PTA) in peripheral arteries such as femoral, popliteal and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures. Contraindications: Hi-Torque wires are not intended for use in the coronary and cerebral vasculature or in patients judged not acceptable for percutaneous intervention.
Device Description	The Hi-Torque Connect guidewire range are disposable medical devices designed for single use only. They consist of a PTFE coated 0.018" diameter stainless steel core wire, one end of which is reduced in diameter in a progressive fashion through a centreless grinding operation. The profile of this reduced section affords the product a reduced area of stiffness and is varied to produce 3 unique levels of support. Each of these 3 levels of support are provided in 3 different length options (145cm – 300cm)

Predicate Devices	**Manufacturer**	**510k**	**Date**
	Hi Torque Connect Guidewire	K112381	03rd Nov 2011

Principle of Operation	The Hi-Torque Connect guidewire is operated manually by a manual process
Comparison of Technological Characteristics	This design change involves a change in the PTFE coating formulation applied to the proximal shaft of the guidewire. No other changes are proposed to the device.
Performance Testing (non-clinical)	In vitro bench tests were carried out to demonstrate equivalence of the existing design to the modified design with reference to the FDAs guidance document “Coronary and Cerebrovascular Guidewire Guidance, Jan 1995”. This testing demonstrates improved coating adhesion properties of the new PTFE coating and that the new process for application of the PTFE coating does not adversely affect other performance characteristics of the wire. The following bench tests were performed: - Tensile Strength

	- Torque Strength - Dimensional Verification - Torque Response - Catheter Compatibility - Coating Adherence/Coating Integrity - Particulate Testing - Tip Flexibility - PTFE Coating Adhesion - PTFE Coating Durability The results from these performance evaluations demonstrated that the Hi-Torque Connect Guidewire range met the acceptance criteria defined in the product specification and performed comparably to the predicate device(s). Biological Safety of the device has been established through successful use of the same materials and manufacturing process in current 510(k) approved Lake Region Medical product.
Conclusions	Based on safety and performance testing, technological characteristics and the indications for use for the device, the Hi-Torque Connect Guidewire has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.