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510(k) Summary – Hi Torque Connect Guidewires
Traditional 510(k)

Device Name	Hi Torque Guidewire
Submitters name	Lake Region Medical Limited, Butlersland, New Ross, Co. Wexford, Ireland.
Application Correspondent	Kenneth Walsh Senior QA/RA Engineer Brivant Ltd, t/a Lake Region Medical International R&D Centre Tel: +353 91 385037 Fax: +353 91 766598
Summary Preparation Date	12th August 2011
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
Boston Scientific, V-18	K033742	12th Jan 2004
Asahi, Treasure	K061984	05th Oct 2006
Asahi, Astato 30	K071721	13th July 2007

Principle of Operation	The Hi-Torque Connect guidewire is operated manually by a manual process

Comparison of Technological Characteristics

The technological characteristics are substantially equivalent to the predicate devices. These performance properties include:

- Same length range provided
- Same diameter (0.018")
- All devices are constructed with a stainless steel core which is reduced in diameter at the distal end to provide flexibility
- The proposed 3 models have equivalent tip stiffness characteristics to the predicate devices.
- All devices have a hydrophilic coating at the distal tip
- All devices have a PTFE coating on the guidewire shaft
- All devices are sterilized using ETO gas

Performance Testing (non-clinical)

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

The following bench tests were performed:

- Tensile Strength
- Torque Strength
- Outer Diameter measurement
- Torque Response
- Catheter Compatibility
- Coating Adherence/Coating Integrity
- Particulate Testing
- Tip Flexibility

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 biocompatibility testing carried out in compliance with ISO 10993-1.

The following biocompatibility tests were performed

Test Description	Test Method
Cytotoxicity Study	Qualitative Evaluation – Dye Exclusion & Microscopial Evaluation
Cytotoxicity Study	Quantitative Evaluation - MTT or XTT Assay
Irritation Test	Intracutaneous Injection (ISO10993-10)
Sensitisation Test	Kligman Maximisation (ISO10993-10)
Acute Systemic Toxicity Test	Systemic Injection ISO10993-11
Acute Systemic Toxicity Test	ISO-Rabbit-Pyrogen
Haemocompatibility Test	Haematology: Haemolysis – rabbit blood– Direct (Complete ASTM Method)
Haemocompatibility Test	Haematology: In-vitro Haemocompatiblity Assay
Haemocompatibility Test	Coagulation: The Prothrombin Time Assay (PT)
Haemocompatibility Test	Coagulation: The Unactivated Partial Thromboplastin Time Assay (UPTT)

	Haemocompatibility Test	Thrombosis: In Vivo Thrombogenicity in Dogs
	Haemocompatibility Test	Complement Activation
	Haemocompatibility Test	Lee& White Coagulation Assay
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.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Lake Region Medical Limited
c/o Kenneth Walsh
Senior QA/RA Engineer
Brivant Limited
Lake Region Medical International R&D Center
Parkmore West Business
Galway, Ireland

Re: K112381
Trade/Device Name: Hi Torque Connect Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 21, 2011
Received: August 17, 2011

Dear Mr. Walsh:

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. However, we remind you 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K112381

Device Name: HI TORQUE GUIDEWIRE

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112381