K092965

Lake Region Medical

PRODUCT: TRAILRUNNER™ GUIDEWIRES
SUBMISSION DATE: SEPTEMBER 10, 2009
SUBMISSION TYPE: TRADITIONAL

FEB 2 6 2010

SECTION 5.0: 510(k) SUMMARY

5.1 MANUFACTURER / REGISTRATION INFORMATION

Lake Region Medical
340 Lake Hazeltine Drive
Chaska, MN 55318-1029 USA
FDA REGISTRATION NUMBER: 2126666

Contact Person: Karen Mortensen
Title: Manager, Regulatory Affairs
Telephone: (952) 448-5111, Extension 6727
Fax: (952) 448-3441

5.2 TRADE NAME (PROPRIETATY NAME)

Lake Region Medical (LRM) produces Guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors.

5.3 DEVICE COMMON NAMES/USUAL NAMES/CLASSIFICATION NAMES

These devices are commonly known as Guides, Guidewires, or spring Guidewires. The current classification names and product codes are Wire, Guide, Catheter (74DQX).

5.4 CLASS OF DEVICE

This type of Guidewire was originally listed as a Class II device by the Neurology (84HAD), the Cardiovascular (74DQX) and the Radiology (74JAJ) Review Panels, respectively.

5.5 IDENTIFICATION OF PREDICATE DEVICE(s)

510(k) NUMBER	MANUFACTURER	DEVICE NAME
K983033	GUIDANT	High Torque BMW Guidewire

5.6 DEVICE DESCRIPTION

The Trailrunner™ Guidewire is comprised of a PTFE coated stainless steel proximal core body and a Nitinol distal core body, joined by a Nitinol hypotube. The distal region of the distal Nitinol core is inserted into the inside diameter of two adjacent, coaxial coils: a platinum coil (distal) and a stainless steel coil (proximal). A stainless steel flat wire (ribbon) is also inserted into the inside diameter of the coils. At the proximal extent of the stainless steel coil, a solder joint binds the coil to the Nitinol core and the flat wire. A second solder joint binds both coils at their junction, the core, and the SS ribbon together, A third solder joint at the distal tip of the device bonds the ribbon to the platinum coil. Depth markings using white PTFE are applied to the proximal end of the core. The distal tip of the guidewire is coated with hydrophilic coating. The 185cm version is designed to mate with the Lake Region extension wire cleared with other Lake Region Guidewires(Reference 510(k);s K970376, K041624)

OUTSIDE DIAMETER: .014"
LENGTHS: 185cm - 300 cm
TIPS: Straight

5.7 TECHNOLOGICAL CHARACTERSTICS

The design specifications are substantially equivalent to the Guidant High Torque BMW Guidewire. Both have a bi-metal core comprised of stainless steel and Nitinol connected by a hypotube. Both designs have a platinum distal coil and a stainless steel coil and both designs have ribbon wires inserted into the inside diameter of the coils. Component joining methods are similar and both are partially coated with hydrophilic coating and contain proximal depth markings on the core.

SECTION 5.0: 510(k) SUMMARY

5.8 COMPLIANCE WITH APPLICABLE STANDARDS

LRM has determined that no mandatory standards, performance standards or special controls have been established for these devices under Section 514 of the Medical Device Amendments to Federal Food, Drug and Cosmetic Act or by any subsequent regulatory action. LRM has also determined that there are no applicable voluntary standards.

5.9 INTENDED USE STATEMENT

For use in Angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.

5.10 COMPARISON

A comparison table to display the similarities and differences of the proposed Trailrunner™ Guidewire to the previously cleared High Torque BMW Guidewires (K983033), to which equivalency is claimed is included in this section.

The table below illustrates the design features for the Trailrunner™ Guidewire iterations and the comparison to the predicate devices:

TRAILRUNNER™ GUIDEWIRES	
PREDICATE DEVICE *CLEARED UNDER K983033*	**PROPOSED DEVICE** *TRAILRUNNER™ GUIDEWIRE PRODUCT LINE*
CORE	
Proximal - PTFE Coated Stainless Steel	Proximal – PTFE Coated Stainless Steel
Distal - Nitinol	Distal - Nitinol
COIL	
Proximal – Stainless Steel (longer length than proposed device) Distal – Platinum Alloy	Proximal – Stainless Steel (shorter length than predicate device) Distal – Platinum Alloy
ADDITIONAL COATINGS	
Hydrophilic	Hydrophilic
JOINING AGENTS	
End joints - Solder Hypotube - Adhesive	End joints - Solder Hypotube - Adhesive
GUIDEWIRE LENGTHS	
190 cm and 300 cm	**185 cm and 300 cm**
DEPTH MARKINGS	
Ablated from PTFE	**White PTFE**
GUIDEWIRE DIAMETER	
.014"	.014"
STERILIZATION METHOD	
Gamma	ETO

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5.11 QUALIFICATION TESTING

NON-CLINICAL TESTS

In order to demonstrate equivalence of the Trailrunner™ Guidewires, LRM performed testing to established requirements. Test pieces were tested and inspected according to established specific inspection criteria requirements for visual/tactile, dimensional and mechanical attributes. The results of these tests demonstrated the functionality and performance characteristics of these Guidewires are comparable to the currently marketed devices.

BIOCOMPATIBILITY TESTING

Biocompatibility testing per ISO 10993 series has been performed on the Trailrunner™ devices and has been found to be acceptable.

5.12 SUBSTANTIAL EQUIVALENCE DATA

Lake Region believes the Trailrunner™ Guidewire is substantially equivalent to the High Torque BMW Guidewire cleared under K983033. All non-clinical test results support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 2 6 2010

Lake Region Medical
c/o Mr. Mark Job
1394 25th St. NW
Buffalo, MN 55313

Re: K092965
Trade Name: Trailrunner™ Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 5, 2010
Received: February 16, 2010

Dear Mr. Job:

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

Enclosure

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K092965

DEVICE NAME: *TRAILRUNNER™ Guidewires*

INDICATIONS FOR USE:
For use in Angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.

PRESCRIPTION USE X *AND/OR* **OVER-THE-COUNTER USE** _____
(Part 21 CFR 801 Subpart D) *(21 CFR 807 Subpart C)*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kirchner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092965