SECTION 2.0 – SUMMARY OF SAFETY AND EFFECTIVENESS

December 21, 2007

K073655

This summary is being included in the Premarket Notification submission in lieu of a statement of availability.

Company Name, Address, and Telephone Number:
Lake Region Manufacturing, Inc. d/b/a Lake Region Medical (LRM) 340 Lake Hazeltine Drive Chaska, MN 55318 Telephone: (952) 448-5111 Fax: (952) 448-3441 Contact Name: Karen Mortensen Manager, Regulatory Affairs Establishment Registration Number: 2126666

JAN 25 2008

Device Trade Name/Proprietary Name:
Pegasus™ Guidewire (Moderate Support and Assert)

Device Common Names/Usual Names and Classification Names:
These devices are commonly known as guides, guidewires, or spring guidewires. The current classification names, and product codes are Angiographic Guidewire (74HAP), Catheter Guidewire (74DQX), and Radiological Catheter Guidewire (74JAJ). Classification of Devices: The classification names listed above were originally classified as Class II devices by the Neurology (84HAD), Cardiovascular (74DQX), and Radiology (90JAJ) Review Panels, respectively.

Applicability of Performance Standards:

LRM has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical 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.

Device Description:

The Pegasus™ steerable guidewires have a nominal diameter of 0.014" and nominal lengths of 185 cm and 300cm. The wire is configured with a radiopaque distal tip and an embedded magnet used with a navigation system to navigate the wire through vasculature. The wire employs a stainless steel proximal core shaft joined to a nitinol distal ground core portion. The distal tip can either be straight or angled. A hydrophilic coating covers the distal portion of the wire and a PTFE coating covers the proximal end of the wire.

The guidewires will be packaged in the standard Lake Region single pack packaging configuration (one wire in a dispenser, placed in a pouch, labeled and then placed in individual cartons). There will be no changes to the sterilization process for these guidewires.

Technological Characteristics:

The design specifications are substantially similar for the Pegasus™ iterations as they are for the Titan™ predicate device with the exception of the blended core material that is joined with a hypotube.

Quality System Controls:

Design Control:
LRM is in conformance with the design control procedure requirements as specified in 21 CFR 820.30. Risk analysis was completed by means of a Failure Mode and Effect Analysis (FMEA) and all verification and validation activities resulted in the ability to demonstrate that the predetermined acceptance criteria were met.

Material/Supplier/Product/Process Controls:
LRM has formal quality systems in place to assure that each product manufactured remains equivalent to the predicate products, and that the changes will not have an adverse affect on the safe and effective use of the product. The quality systems include Engineering Change Order Review, Material Qualification, Supplier Qualification, Product Qualification, and Process Qualification. These controls are applied to each product size/group.

Qualification Testing:

Non-Clinical Tests:
In order to demonstrate equivalence of the Pegasus™ iterations, LRM and Stereotaxis 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 Pegasus™ device and has been found to be acceptable.

Substantial Equivalence Data:

Lake Region believes the Pegasus™ iterations are substantially equivalent to the Titan™ predicate devices cleared under 510(k) K060454. Performance specification changes to the Pegasus™ iterations are directly related to the blended material core design. All non-clinical test results support the claim of substantial equivalence to the predicate devices.

Intended Use Statement:

Pegasus™ steerable guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.

NOTE: The modification of this device does not alter its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lake Region Manufacturing, Inc.
c/o Ms. Karen Mortensen
Manager, Regulatory Affairs
340 Lake Hazeltine Drive
Chaska, MN 55318

JAN 2 5 2008

Re: K073655
Trade Name: Pegasus™ Steerable (PTCA) Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: December 21, 2007
Received: December 26, 2007

Dear Ms. Mortensen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): K073655

Device Name: Steerable Guidewire (Trade Name: Pegasus™)

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)

Susan R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073655