K042338

SEP 16 2004

SECTION 2.0 – SUMMARY OF SAFETY AND EFFECTIVENESS

August 25, 2004

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. (LRM)
340 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952) 448-5111 Fax: (952) 448-3441

Contact Name: Karen Mortensen
Senior Regulatory Compliance Specialist

Establishment Registration Number: 2126666

Device Trade Name/Proprietary Name:

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. Consequently there are a large number of trade and proprietary names not including or associated with LRM. LRM has no proprietary names of its own to be included with this submission.

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.

Labels, Labeling and Advertising:

LRM produces cardiovascular and vascular guidewires on an OEM basis for other manufacturers kit assemblers and distributors. There is no direct distribution by LRM. Changes to the customer controlled labels labeling or promotional materials are at their discretion including the resolution of any resulting regulatory obligations. A fraction of the total production bears LRM controlled labels and labeling.

Device Description:

This device is a guidewire with a PTFE coated stainless steel core that has been ground at the distal end to provide the appropriate tip flexibility. Radiopaque marker coils are joined to the core at the ground end and a distal tip coil is soldered to the core. The proximal PTFE coated portion of the core has two sections of the PTFE removed to aid in estimating guidewire positioning.

The product is offered with a shapeable straight tip or in a preshaped configuration. The guidewires are optionally coated with MDX (silicone). The guidewires are bound by the following parameters:

Outside Diameter:	.014" - .018"
Lengths:	130cm – 300cm
Tips:	Straight or shaped with various tip flexibilities

Engineering Specifications:

The design specifications are the same for the proposed device as they are for the LRM predicate device [reference 510(k)s K022813 and K011968] with the exception of the smaller outer diameter and the additional radiopaque marker coils soldered to the core proximal to the existing radiopaque coil. The finished device must meet the same basic design criteria as the predicate device.

Substantial Equivalence Data:

Lake Region believes this device is substantially equivalent to the predicate device. The table below lists the differences between the predicate device and the proposed device. Testing was done to ensure the changes to the device met the predetermined acceptance criteria.

Item	**Proposed Device Differences from LRM Predicate cleared under 510(k) K022813**
Raw Materials	Core: No change to raw material Coils: No change to raw material
Assembly Process	No change to assembly processes **with the exception of the additional solder step to join the additional radiopaque marker coils to the core.**
Physical Characteristics	No change **except to offer a .014" along with the .018" diameter.**
Labeling/IFU	No change to the labeling/IFU **except to change the description to add the smaller diameter.**
Intended Use	No change to intended use
Anatomical Sites	No change
Target Population	No change
Performance Testing	No change
Safety Characteristics	No change
Biocompatibility	No change
Risk Analysis	No change

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/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, 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 proposed device, 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:
There are no new materials used in the modification of this device. Biocompatibility testing has been performed on the predicate product and has been found to be applicable to the modified device. This testing, along with a market history of proven biocompatibility, establishes acceptable biocompatibility for this device.

Packaging and Sterilization Information:

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by LRM. A portion of the production is private label, sterile packaged to customer specifications, some of that product is provided sterile to the customer.

The single packaged guidewire is placed in a dispenser and then into a Tyvek®/poly pouch. The packaged product may be packaged as five or ten pouches in a shelf carton, which are typical packaging configurations.

There will be no changes to the sterilization process for the portion of packaged product shipped sterile to the customer. For the product that is shipped bulk, the packaging design and sterilization process parameters are the customer's responsibility. LRM will not recommend that its customers modify their packaging or sterilization procedures as a result of this submission.

Intended Use Statement:

Lake Region's steerable guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature, including the renal vasculature. The steerability feature allows the guidewire to be torqued to facilitate navigation through the 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

SEP 16 2004

Lake Region Manufacturing, Inc.
c/o Ms. Karen Mortensen
Senior Regulatory Compliance Specialist
340 Lake Hazeltine Drive
Chaska, MN 55318

Re: K042338
Trade/Device Name: Coronary, Peripheral and Renal Steerable Hydrophilic Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: August 27, 2004
Received: August 30, 2004

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 Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.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): K042338

Device Name: Coronary Periperal and Renal Steerable Hydrophilic Guidewire

Indications For Use:

Lake Region's steerable guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature, including the renal vasculature. The steerability feature allows the guidewire to be torqued to facilitate navigation through the 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. Vollmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042338