MAY 17 2004

K040825

SECTION 2.0 – SUMMARY OF SAFETY AND EFFECTIVENESS

March 26, 2004

2.1 General Information

2.1.1 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

2.1.2 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.

2.1.3 Device Common Names/Usual Names and Classification Names

These devices are commonly known as coronary and peripheral catheter guidewires. The current classification names and product codes are Wire, Guide, Catheter (74DQX).

2.1.4 Establishment Registration Number: 2126666

2.1.5 Classification of Devices

Catheter guidewires have been classified as Class II devices by the Circulatory Systems Devices Panel (reference 21 CFR 870.1330).

2.1.6 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.

2.2 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 material are at their discretion, including the resolution of any resulting regulatory obligations. A fraction of the total production bears LRM controlled labels and labeling.

2.3 Statement of Availability

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

2-4 Device Description

2.4.1 The Lake Region Hydrophilic Guidewire consists of a flexible, tapered core wire that decreases in outer diameter from the proximal to the distal end. The hydrophilic coating reduces friction during use. The radiopaque distal coil facilitates fluoroscopic visualization. The Lake Region Hydrophilic Guidewire will be available in two configuration, with either an outer diameter of 0.010" or 0.014" and 180cm long.

The guidewire dimensions are as follows:

Product Description	Shaft OD (nominal)	Shaft Length (nominal)	Coil Length (nominal)
0.010" Guidewire	.010"	180 cm	10 cm
0.014" Guidewire	.014"	180 cm	10 cm

2.4.2 Engineering Specifications

The design specifications are the same for the proposed device as they are for the predicate device (K003084). The finished devices must meet the same basic design criteria.

2.5 Substantial Equivalence Data

2.5.1 Background Information

The proposed device is the same device as the predicate device. Lake Region manufactured the predicate device for Concentric Medical and Concentric Medical contracted with Lake Region to do the design validation testing. Therefore, the majority of the information supplied in the Concentric Medical 510(k) submission originated with Lake Region Manufacturing.

2.5.2 Comparison table of predicate to proposed device

Item	Proposed Device Differences from Predicate cleared under 510(k) K003084
Raw Materials	No change
Assembly Process	No change
Physical Characteristics	No change
Labeling/IFU	**The only change to the IFU will be to the manufacturer information and the omission of the optional introducer information.**
Intended Use	No change
Anatomical Sites	No change
Target Population	No change
Performance Testing	No change
Safety Characteristics	No change
Biocompatibility	No change
Risk Analysis	No change

2.6 Design Control and Validation Activities

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 could be met.

As there were no changes to the device itself and Lake Region conducted the original design verification testing used to establish safety and effectiveness under Concentric Medical Hydrophilic Guidewire K003084, no further testing has been required.

2.7 Material/Product/Process Qualification

LRM has formal quality systems in place to assure that the proposed product will remain equivalent to the predicate 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.

2.8 Biocompatibility Testing

The materials for the proposed device are identical to the predicate device cleared under K003084 and are identically processed and sterilized. Therefore, biocompatibility testing for the proposed device is not required.

2.9 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, a fraction 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 singlely or in five or ten pouchs to 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.

2.10 Intended Use Statement

The intended use statement is the same as the intended use statement for the predicate device cleared under K003084, specifically:

The Lake Region Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the coronary, peripheral, visceral and cerebral vasculature.

2.11 Conclusion

The Lake Region Hydrophilic Guidewire is substantially equivalent to the predicate guidewire cleared under 510(k) K003084. There have been no significant changes to the guidewire design as previously manufactured by Lake Region Manufacturing for Concentric Medical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

Lake Region Manufacturing, Inc.
c/o Karen Mortensen
Senior Regulatory Compliance Specialist
340 Lake Hazeltine Drive
Chaska, MN 55318-1029

Re: K040825
Lake Region Hydrophilic Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 26, 2004
Received: March 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,

Donna R. Vochnes

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

Indications for Use

510(k) Number (if known): K040825

Device Name: Hydrophilic Guidewire

Indications For Use:

The Lake Region Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the coronary, peripheral, visceral and cerebral vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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. Vochmes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040825