

K970376

SECTION 2.0 - SUMMARY & CERTIFICATION

JUN - 6 1997

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: 612/448-5111 Fax: 612/448-3441

2.1.2 Device Trade Name/Proprietary Name

LRM produce 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/Unusual Names, Classification Names

These devices are commonly known as coronary catheter guidewires and accessories.

2.1.4 LRM Establishment Registration Number: 2126666

2.1.5 Classification of Devices

Catheter guidewires have been classified as Class II be 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 Device Amendments to the Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action.

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 small fraction of the total production bears LRM controlled labels and labeling.

2.3 Summary of Safety and Effectiveness

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

2.4 Device Description

2.4.1 Description of Guidewires

The guidewire is a steerable PTFE coated stainless steel core wire; the distal portion may be either a 30 cm long stainless steel outer coil with a 2 cm long platinum inner coil to provide radiopacity, or a 30 cm long platinum coil for radiopacity; the tip may be either a straight, shapable configuration or a preshaped J configuration. The guidewires are coated with MDX (silicone). The guidewires are bound by the following parameters:

Outside Diameters: .014" - .018"
Lengths: 175 cm - 300 cm
Tips: Straight, Shapable and J
Flexibility: Floppy to Support

2.4.2 Description of the Guidewire Extension and Alignment Tool

The guidewire extension is a PTFE coated stainless steel wire with a connector at the distal end and is bound by the following parameters:

Outside Diameter: .014" - .018"
Length: 145 cm

The alignment tool is a slit rubber or silicone cylinder which assists in the placement of the guidewire pin into the extension connector.

2.4.3 Engineering Specifications

The design specifications are the same for the products offered by LRM as when they were offered by Baxter. The finished devices must meet the same design criteria. Additional diameter offerings in the .016" and .018" range have been added to the product options. Section 2.5 contains comparative data.

2.5 Substantial Equivalence Data

2.5.1 Background Information

In order to demonstrate equivalence of the products, LRM performed physical/mechanical testing to support this submission.

2.5.2 Test Data

Within each product group, there were twenty (20) samples selected. The following tests were performed:

- 2.5.2.1 Dimensional Measurement: Micrometer measurement of the outside diameter of the guidewire at multiple body points.
- 2.5.2.2 Distal Tip Flexibility: Assess the flexibility of a distal tip.
- 2.5.2.3 Torsional Integrity: Assess the torqueable strength of a guidewire.
- 2.5.2.4 Coating Durability: Measures the number of controlled abrasion strokes necessary to cause deformation or removal of PTFE coating.
- 2.5.2.5 Rotational Control: Assess guidewire rotational control (clockwise or counter clockwise) to allow placement of the distal tip at a desired location in a 360°circle when controlled from the proximal end of the guidewire.
- 2.5.2.6 Guidewire Pull Test: Measures the strength of the joints of the guidewire.
- 2.5.2.7 Three Point Bend: Measures stiffness/flexibility of guidewire body.
- 2.5.2.8 Extension Joint Coupling: Assess ease of joint connection.
- 2.5.2.9 Catheter/Extension Joint Interface: Confirm clearance and smooth transition of extension joint relative to the catheter.
- 2.5.2.10 Extension Joint Integrity: Assess extended guidewire joint functionality.

RESULTS: All test results were within prescribed specification limits.

2.6 Qualification and Test Data

2.6.1 Material/Product/Process Qualification

LRM has formal quality systems in place to assure that each of the products manufactured remain equivalent to the predicate products and that there will be no adverse affects on the safe and effective use of the products. the quality systems include Engineering Change Order Review, Material Qualification, Product Qualification, and Process Qualification. These controls are applies to each product size/group.

2.6.2 Biocompatibility Testing

LRM has adapted the biocompatibility testing recommendations in the FDA's DRAFT "Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices" dated May, 1993.

The following table lists the tests that were performed and the test results.

TEST PERFORMED	TEST RESULTS
Acute Systemic Toxicity	No signs or symptoms of Systemic Toxicity were observed for any of the samples
Cytotoxicity	The sampled passed per current USP
Hemolysis	The samples did not produce hemolysis
Intracutaneous Test	For all samples, skin reactions were not significant
Physico-Chemical	The samples passed per current USP
Thromboresistance	The samples were not considered thrombogenic
Chemical Analyses	The samples meet specifications
Pyrogen test	The products did not produce a pyrogenic response

2.7 Packaging and Sterilization Information

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is limited direct distribution by LRM. A portion of the production is private label, single packaged to customer specifications, a portion of that product is provided sterile to the customer.

The single packaged guidewire and extension wire are placed in a polyethylene dispensers and then into a Tyvek®/poly pouch. The product may be packaged as five (5) pouches in a shelf carton (five pack), which is a typical packaging configuration.

There will be no changes to the sterilization process for the portion of the product shipped sterile to the customer. for 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 the packaging or sterilization procedures as a result of this submission.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 1997

Ms. Kim Aves
Lake Region Manufacturing, Inc.
340 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K970376
PTCA Guidewire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: April 3, 1997
Received: April 4, 1997

Dear Ms. Aves:

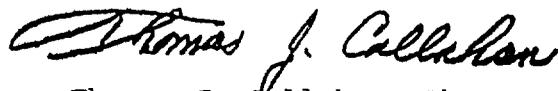
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): Unknown

Device Name: Steerable Guidewire and Extension Wire

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.

The attachment of the guidewire extension to the Lake Region Steerable guidewire creates a guidewire that can be used to exchange a catheter without removing the guidewire from the vessel. When the exchange is complete, the guidewire extension can be detached and the original guidewire can again be used in a conventional manner.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory
and Neurological Devices
510(k) Number K970376

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____