

JUN 5 1998

SECTION 2.0 - SUMMARY & CERTIFICATION

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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 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 guides, guidewires, or spring guidewires. The current classification name, and product code is Gastroenterology-Urology Catheter Accessory (78KOD).

2.1.4 LRM Establishment Registration Number: 2126666

2.1.5 Class of Device

This type of guidewire was originally listed as Class II devices by the Gastroenterology-Urology Review Panel (21CFR 876.5130).

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

2.3 Summary of Safety and Effectiveness

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

2.4 Device Description

2.4.1 Description of Guidewire

Nickel Titanium steerable core with a clear or colored, radiopaque jacket, with a polymer/hydrophilic coating is applied over the core/jacket. The guidewires are bound by the following parameters:

<i>Outside Diameter:</i>	<i>.018" - .038"</i>
<i>Lengths:</i>	<i>150 cm - 400 cm</i>
<i>Tips:</i>	<i>Straight or shaped with standard or long taper tip flexibility</i>

Note: None of these guidewires are for PTCA use.

2.4.2 Engineering Specifications

The design specifications are the same for guidewires manufactured with or without the polymer/hydrophilic coating. The finished devices must meet the same design criteria. Section 2.5 contains comparative data to demonstrate equivalency.

2.5 Substantial Equivalence Data

2.5.1 Background Information

In order to demonstrate equivalence of guidewires manufactured with polymer/hydrophilic, LRM performed comparative testing between LRM hydrophilic guidewires and Terumo guidewires.

LRM chose a product mix of three groups of wires, based on the available Terumo products of .018", .035" and .038" standard configurations, including straight and shaped distal tips. LRM samples were produced following current manufacturing processes and procedures. Terumo product was purchased by LRM, complete in packaging. All samples were sterilized prior to testing.

2.5.2 Comparative Test Data

Within each of the three groups, production samples were made representing the minimum (smallest size), maximum (largest size) and mode (most common size). For each test series, samples were produced per standard manufacturing procedures. For each test type, either fifteen (15) or ten (10) test samples were selected. Some of the tests are destructive in nature which required the selection of additional sets of fifteen (15) or ten (10) samples to perform other tests.

The following product qualification tests were performed:

- 2.5.2.1 Visual: Assess the visual appearance of the product for polymer tip integrity and jacket durability (cuts, splits, seams, etc., any indication that the tip has been compromised).
- 2.5.2.2 Dimensional Measurement - Outside Diameter, Dry and after 10 minutes soak and after 40 minute soak in normal saline : Micrometer measurement of the outside diameter of the guidewire at multiple body points.
- 2.5.2.3 Lubricity: Measures the force required to insert and withdraw the guidewire within a catheter lumen standardized to each guidewire diameter.
- 2.5.2.4 Pull Test: Measures the strength of welded joint points in the guidewire.
- 2.5.2.5 3-Point Bending Test: Assess guidewire body stiffness/flexibility.
- 2.5.2.6 Coating Durability: Measures the lubricity before and after multiple catheter insertions and withdrawals.
- 2.5.2.7 Distal Tip(J) Memory: Assess the memory of the distal tip form of shaped product.
- 2.5.2.8 Kink Resistance: Measures the kink resistance properties of product made from kink resistance materials or products that are designed to have kink resistance properties.
- 2.5.2.9 Linear Stiffness: Measures the linear tip flexibility.
- 2.5.2.10 Torque Control: Assess guidewire torque response and rotational control to allow placement of the distal tip at a desired location in a 360 degree circle when controlled from the proximal end of the guidewire. Control may be clockwise or counter-clockwise.
- 2.5.2.11 Torque Fatigue: Assess the torqueable strength of a guidewire.

RESULTS: All test results were within prescribed specification limits.

2.6 Qualification and Biocompatibility Test Data

2.6.1 Material/Product/Process Qualifications

LRM has formal quality systems in place to assure that each product manufactured with the polymer/hydrophilic coating remain equivalent to the predicate product, 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.

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2.6.2 Biocompatibility Testing

LRM has adapted the biocompatibility testing recommendations in the FDA's General Program Memorandum #G95-1 Use of international Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", dated May 1, 1995.

The following table lists the test 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 (MEM)	The samples evoked a mild cytotoxic response (Grade 1), when tested at 48 hours. The test material passed the assay.
Hemolysis	The samples did not produce hemolysis.
Intracutaneous Test	For all samples, skin reactions were not significant.
Pyrogen (Material Mediated)	The samples did not produce a pyrogenic response.
Inhibition and Enhancement	No endotoxin detected at 0.03 eu/ml
Sensitization	The samples were deemed to be a non-sensitizer.
Thrombo In-Vitro (Plate Method)	The test article was considered nonthrombogenic

2.7 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 small portion of the production is private label, single packaged to customer specifications, a fraction of that product provided sterile to the customer.

The single packaged polymer/hydrophilic coated guidewires s placed in a dispenser and then into a Tyvek/poly pouch, along with a tray containing a torque device. The product may be packaged as five 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 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.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Kim E. Aves
Regulatory Compliance Manager
Lake Region Manufacturing, Inc.
340 Lake Hazeltine Drive
Chaska, MN 55318Re: K981667
LRM Hydrophilic Coated Guidewire
Dated: May 8, 1998
Received: May 11, 1998
Regulatory Class: II
21 CFR 876.5130/Procode: 78 KNY

Dear Ms. Aves:

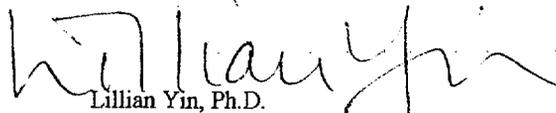
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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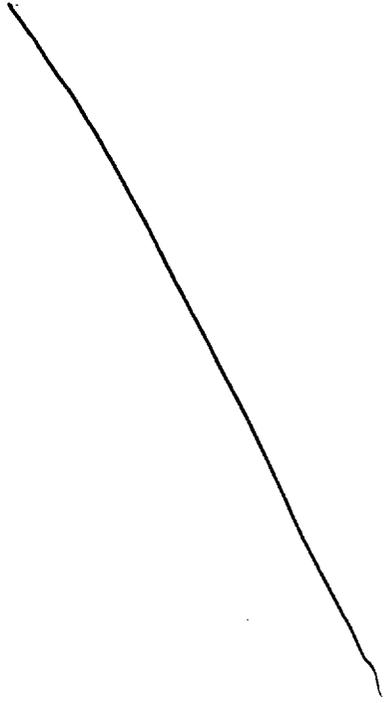
510(k) Number (if known): Unknown

Device Name: Hydrophilic Coated Guidewire

Indications for Use:

To facilitate the placement of devices during diagnostic and interventional procedures.

NOTE: These guidewires are not intended for PTCA use.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Rathbone

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981667

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)