

K971322
July 22, 1998
SECTION 2.0 - SUMMARY & CERTIFICATION

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 included 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 names, and product codes are Angiographic Guidewire (74HAP), Catheter Guidewire (74DQX), and Radiological Catheter Guidewire (74JAJ).

2.1.4 LRM Establishment Registration Number: 2126666

2.1.5 Classification of Devices

The classification names listed above were originally listed as Class II device by the Neurology (84HAD), Cardiovascular (74DQX), and Radiology (90JAJ) review panels.

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 portion 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 CCA Guidewire products

NiTi core with stainless steel or platinum coil secured to the ground, flexible (distal) end of the core. The guidewires are bound by the following parameters:

Outside Diameter:	.014" - .045"
Length:	20 cm - 500 cm
Tip:	Straight, Shapable or Preshaped
Flexibility:	Soft through Stiff
Coil Length:	2 cm - 30 cm

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 a NiTi core or platinum coil. 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 substantial equivalence of guidewires manufactured with a NiTi core and platinum coil, LRM performed comparative testing between LRM guidewires and Flexmedics guidewires.

LRM chose a product mix of three groups of LRM manufactured wires and two groups of Flexmedics product, based on the available Flexmedics products of .014" and .018" configurations. LRM samples were manufactured following current manufacturing processes and procedures. Flexmedics products were purchased by LRM, complete in packaging. All samples were sterilized prior to testing.

2.5.2 Comparative Test Data

Within each of the groups, production samples were made; at least two hundred (200) samples of each size (600+ total samples) were produced per standard manufacturing procedures. For each test, there were 30 samples selected. Some of the tests are destructive in nature which requires the selection of additional sets of 30 samples to perform other tests.

The following product qualification tests were performed:

- 2.5.2.1 Visual: Assess the visual aspects of the product.
- 2.5.2.2 Dimensional Measurement - Outside Diameter: Micrometer measurement of the outside diameter of the product at multiple body points.
- 2.5.2.3 Distal Tip Flexibility: Assess the flexibility of the product's distal tip.
- 2.5.2.4 Kink Resistance: Assess the kink resistance of the core wire.
- 2.5.2.5 Torsional Integrity: Assess the torsional strength of the product.
- 2.5.2.6 Pull Test: Measures the strength of the distal and proximal joints of the product.
- 2.5.2.7 3-Point Bending Test: Assess the product's body stiffness/flexibility.

RESULTS: All test results were within prescribed specification limits.

2.6 Qualification and Biocompatibility 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 product, and that the change 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.

2.6.2 Biocompatibility Testing

LRM has adapted the biocompatibility testing recommendations in the FDA's General Program Memorandum #G95-1, Subject: 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 tests that were performed and the test results.

TEST PERFORMED	TEST RESULTS
Cytotoxicity	The sample evoked no cytotoxic response (Grade 0)
Hemolysis	The sample produced no hemolysis
Acute Systemic Toxicity	No signs or symptoms of systemic toxicity were observed
Intracutaneous Test	For all samples, the skin reactions were not significant.
Implantation (7 Day)	The reaction was not significant as compared to the negative control implant, for any of the samples.
Sensitization	The samples were deemed to be a non-sensitizer.
Pyrogen Test	The samples did not produce a pyrogenic response.

2.7 Packaging and Sterilization Information

LRM produce 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 is provided sterile to the customer.

The single packaged CCA 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 the 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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kim Aves
Regulatory Affairs Associate
Lake Region Manufacturing, Inc.
340 Lake Hazeltine Drive
Chaska, MN 55318

Re: K971322
Trade Name: Core and Coil Assembly (CCA) Guidewire
Regulatory Class: II
Product Code: DQX
Dated: April 21, 1998
Received: April 23, 1998

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 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). 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

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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) 594-4618. 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" (21CFR 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,



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: Core and Coil Assembly Guidewire (CCA)

Indications for Use:

For percutaneous entry of peripheral vessel using the Seldinger technique.

T. A. R.
 (Division Sign-Off)
 Division of Cardiovascular, Respiratory,
 and Neurological Devices
 510(k) Number K971322

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 32 CFR 801.109)

OR

Over-The Counter Use _____