

K960718

SECTION 2.0 - SUMMARY & CERTIFICATION

MAY 21 1996

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/Unusual 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 classified as Class II devices by the Neurology (84HAD), Cardiovascular (74DQX), and Radiology (90JAJ) Review Panels respectively.

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 Guidewires Produced With Polymer/Hydrophilic Coating

Steerable stainless steel core with radiopaque marker; a jacket, and polymer/hydrophilic coating is applied over the core/coil. The guidewires are bound by the following parameters:

Outside Diameter:	.016" - .045"
Lengths:	20 cm -- 400 cm
Tips:	Straight, Shapable with standard and stiff tip flexibility

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 polymer/hydrophilic guidewire and Terumo guidewires.

LRM chose a product mix of three groups of wires, based on the available Terumo products of .018" standard, .035" standard and .038" stiff configurations. LRM samples were manufactured 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; at least two hundred (200+) samples of each size (600+ total samples) were produced per standard manufacturing procedures. For each test, there were either twenty (20) or thirty (30) samples selected. Some of the tests are destructive in nature which required the selection of additional sets of twenty (20) or thirty (30) samples to perform other tests.

The following product qualification tests were performed:

- 2.5.2.1 Lubricity: Measures the force required to insert and withdraw the guidewire within a catheter lumen standardized to each guidewire diameter.
- 2.5.2.2 Coating Durability: Measures the lubricity before and after multiple catheter insertions and withdrawals.
- 2.5.2.3 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.
- 2.5.2.4 Distal Tip Flexibility: Assess the flexibility of the distal tip.
- 2.5.2.5 3-Point Bending Test: Assess guidewire body stiffness/flexibility.
- 2.5.2.6 Rotational Control: Assess guidewire 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.
- 2.5.2.7 Torsional Integrity: Assess the torqueable strength of a guidewire.
- 2.5.2.8 Radiopacity: Assess the radiopacity of the distal tip, to establish equivalency to currently marketed hydrophilic guidewires.
- 2.5.2.9 Tracking: Assess the tractability of Lake Region's hydrophilic guidewire.
- 2.5.2.10 Pull Test: Measures the strength of welded joint points in the 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 of the products 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.

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 test that were performed and the test results.

TEST PERFORMED	TEST RESULTS
Cytotoxicity	The samples evoked a mild cytotoxic response (Grade 2) when tested at a 48 hour exposure period. The test material passed the assay.
Hemolysis	The samples did not produce hemolysis.
Acute Systemic Toxicity	No signs or symptoms of Systemic Toxicity were observed for any of the samples.
Intracutaneous Test	For all samples, 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.