K013284

FEB 1 1 2002

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: TBD

Applicant Information:

Date Prepared:	September 26, 2001
Name:	LuMend, Inc.
Address:	400 Chesapeake Drive Redwood City, CA 94063 650-364-1400
Contact Person:	Michael A. Daniel
Phone Number:	(415) 407-0223
Facsimile Number:	(925) 932-5706

Device Information:

Classification:	Class II Percutaneous Catheter
Trade Name:	LuMend Frontrunner™ CTO Coronary Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Devices:

The LuMend Frontrunner™ CTO Coronary Catheter is substantially equivalent in intended use and/or method of operation to a combination of the following predicate devices:

1. **Spectranetics Support Catheter** Spectranetics Corp. – 510(k) K991059
2. **Magnum-Meier™ Recanalization Guidewire** Schneider AG / Pfizer Hospital Prod. – 510(k) K911547
3. **Clyde™ Coronary Guidewire** Schneider (Europe) AG / Pfizer Hospital Prod. Group – 510(k) K970528
4. **USCI Adjustable Tip Guide Wire** C.R. Bard, Inc. – 510(k) K884647

Device Description:

The LuMend Frontrunner™ is a sterile single-use percutaneous coronary catheter consisting of a handle assembly with an integral rotator and a side port for internal device flushing, a proximal

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and a radiopaque blunt-shaped distal variable-size tip assembly. A handle lever provides manual adjustment of the size of the tip assembly, and the handle rotator provides rotational control for the shaft and distal tip assembly. The distal assembly consists of a set of bilateral hinged tip pieces. The Frontrunner catheter does not have a guide wire lumen. Guidance and tracking of the catheter through the coronary vasculature is accomplished by selective manual shaping of the flexible distal shaft, and controlled torquing of the handle rotator.

Intended Use:

The LuMend Frontrunner™ CTO Coronary Catheter is intended to facilitate the intra-luminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) prior to PTCA or stent intervention.

Comparison to Predicate Device(s):

The LuMend Frontrunner™ CTO Coronary Catheter is substantially equivalent to a combination of the Spectranetics Support Catheter (K991059), the Schneider AG / Pfizer Hospital Products Magnum-Meier™ Recanalization Guidewire (K911547) and Clyde™ Coronary Guidewire (K970528) and the C.R. Bard, Inc. USCI Adjustable Tip Guide Wire (K884647).

The LuMend Frontrunner™ is substantially equivalent to the Clyde™ Coronary Guidewire (K970528) in terms of intended use. The Clyde Guide wire is intended to reach and cross stenotic lesions prior to use of PTCA and / or stent therapeutic devices. The LuMend Frontrunner is intended to facilitate the intra-luminal placement of guide-wires beyond stenotic lesions. In the case of the Clyde™ device, once the lesion has been crossed, a balloon dilatation catheter may be immediately introduced along the guide wire. In the case of the LuMend Frontrunner™, the device must be removed and replaced with a conventional guide wire prior to insertion of a PTCA device.

The LuMend Frontrunner™ device is substantially equivalent to the USCI Adjustable Tip Guide Wire in terms of the incorporation of a "pull wire" in the internal lumen used to deflect the distal tip of the catheter. Both the USCI Adjustable Tip Guide Wire and the LuMend Frontrunner devices provide the ability to deflect the distal tip *in situ*.

The Frontrunner™ device is substantially equivalent to the Magnum Meier™ Recanalization Guide Wire in that it provides a spherically shaped distal tip to bluntly dissect stenotic tissue. The Magnum Meier instructions for use explicitly discusses the use of the guide wire in conjunction with a supporting catheter and advancing the recanalization wire either by itself or along with the catheter. The option of expanding the size of the Frontrunner distal tip is similar in affect to exchanging smaller guide wires for larger diameter wires.

The LuMend Frontrunner™ is similar in terms of shape, size, materials and construction to common coronary catheters used to provide guide wire support.

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***In Vitro*, *In Situ* and *In Vivo* Test Data:**

Design analysis, *in vitro* and *in vivo* data confirm that basic functional characteristics are substantially equivalent to the predicate devices cited. Device evaluation consisted of testing specified in FDA's Coronary and Cerebrovascular Guidewire Guidance Document (January 1995) and included *in vitro* tensile, torque strength, torqueability, tip flexibility, coating adherence/integrity, biocompatibility and catheter compatibility. All data fell well within both internal specification requirements, as well as external standard requirements and predicate performance expectations.

In addition to the above testing, a series of clinical studies have demonstrated substantial equivalence in terms of device safety and effectiveness .

Summary:

Based upon the product technical information, intended use, performance and biocompatibility information provided in this pre-market notification, the LuMend Frontrunner™ has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2002

Mr. Michael A. Daniel
LuMend, Inc.
400 Chesapeake Drive
Redwood City, CA 94063

Re: K013284
LuMend Frontrunner™ CTO Coronary Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: December 24, 2001
Received: December 26, 2001

Dear Mr. Daniel:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

510(k) Number (if known): K013284 TBD

Device Name: LuMend Frontrunner™ CTO Coronary Catheter

Indications For Use:

The LuMend Frontrunner™ CTO Coronary Catheter is intended to facilitate the intra-luminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) prior to PTCA or stent intervention.

(D... ...on of Cardiovascular, Respiratory, Neurological Devices

(...) Number K013284

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)