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2. 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 K033535

Applicant Information:

Date Prepared:	November 7, 2003
Name:	LuMend, Inc.
Address:	400 Chesapeake Drive Redwood City, CA 94063 650-364-1400
Contact Person:	Michael A. Daniel
Phone Number:	Office: 925-254-5228 / Cell 415-407-0223
Facsimile Number:	(925) 254-5187

Device Information:

Classification:	Class II Percutaneous Catheter
Trade Name:	LuMend Frontrunner® CTO Catheter and Accessories
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Devices:

The LuMend Frontrunner® CTO Catheter and Accessories is substantially equivalent in intended use and method of operation to the following predicate device:

LuMend Frontrunner® CTO Catheter K031005

Device Description:

The LuMend Frontrunner® CTO Catheter is a sterile single-use percutaneous catheter consisting of a handle assembly with an integral rotator and a side port for internal device flushing, a proximal braided shaft for push and torque control, a flexible distal shaft which may be manually shaped, an optional guide wire lumen and a radiopaque blunt-shaped distal variable-size tip assembly in various shapes and sizes. 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. Guidance and

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tracking of the catheter through the coronary or peripheral vasculature is accomplished by selective manual shaping of the flexible distal shaft, and controlled torquing of the handle rotator and/or the use of a guide wire.

Intended Use:

The LuMend Frontrunner® CTO Catheter and Accessories are intended to facilitate the intra-luminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) in the peripheral and coronary vasculature prior to further percutaneous intervention.

Comparison to Predicate Device(s):

The LuMend Frontrunner® CTO Catheter and Accessories are substantially equivalent to the previously cleared LuMend Frontrunner® CTO Catheter in terms of embodiment, shape, appearance and function. It has the same indications for use and makes use of the identical mechanism of action: "blunt micro-dissection" to facilitate placement of a guide wire across stenotic vascular lesions including Chronic Total Occlusions (CTOs).

***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 device cited. Routine device evaluation consists 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 tests. All data continued to fall well within internal specification requirements, as well as external standard requirements and predicate performance expectations.

Summary:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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LuMend, Inc.
c/o Mr. Michael A. Daniel
Regulatory and Clinical Affairs
400 Chesapeake Drive
Redwood City, CA 94063

Re: K033535
LuMend Frontrunner® CTO Catheter and Accessories
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 10, 2003
Received: December 11, 2003

Dear Mr. Daniel:

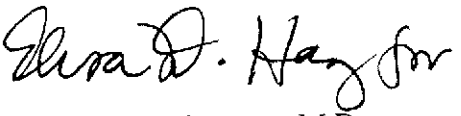
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



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

Enclosure

4. INDICATIONS FOR USE FORM

510(k) Number (if known): TBD K033535

Device Name: **LuMend Frontrunner® CTO Catheter and Accessories**

Indications For Use:

The LuMend Frontrunner® CTO Catheter and Accessories are intended to facilitate the intra-luminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) in the peripheral and coronary vasculature prior to further percutaneous intervention.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K033535 (SM. K)

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

(Optional Format 1-2-96)