JAN 1 6 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.

K011562

510(k) Number: TBD

Applicant Information:

Date Prepared: May 18, 2000

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 Percutaneous Catheter -TBD
Common Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Devices:

The LuMend Percutaneous Catheter is substantially equivalent in intended use and/or method of operation design and materials to a combination of the following predicate devices:

1. ILT™ 0.014" Catheter (K001992),
2. Medtronic Zuma™ Guiding Catheters (K000677) and
3. Guidant Viking Optima™ Guiding Catheter (K001435)

Device Description:

The LuMend Percutaneous Catheter is a sterile single-use percutaneous coronary catheter consisting of a guide wire lead and handle assembly, proximal and distal shaft and variably curved distal tip. Guidance and tracking of the catheter through the coronary vasculature is accomplished in conjunction with a steerable guide wire.

(Continued)

Intended Use:

The LuMend Percutaneous Catheter is intended to be used in conjunction with a steerable guide wire in order to access discreet regions of the coronary vasculature. It may be used to facilitate placement of guide wires and other interventional devices.

Comparison to Predicate Device(s):

The LuMend Percutaneous Catheter is substantially equivalent to a combination of the ILT™ 0.014" Catheter (K001992), the Medtronic Zuma™ Guiding Catheters (K000677) and the Guidant Viking Optima™ Guiding Catheter (K001435).

The LuMend Percutaneous Catheter is essentially identical to the ILT™ 0.014" Catheter (K001992), in terms of intended use. Both devices are primarily intended to be used in conjunction with a steerable guide wire in order to access discreet regions of the vasculature prior to angioplasty and stenting. In both cases once the vasculature has been navigated and any lesion has been crossed, alternative conventional guide wires may be exchanged and a balloon dilatation catheter may be immediately introduced.

The LuMend Percutaneous Catheter is similar in terms of shape, size, materials and construction to common coronary catheters used to provide guide wire and other catheter support and guidance. Examples of these devices include both the Medtronic Zuma™ Guiding Catheters (K000677) and the Guidant Viking Optima™ Guiding Catheter (K001435) in terms of size ranges, design, materials used, form and function.

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

Design analysis and *in vitro* 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.

Summary:

Based upon the product technical information, intended use, and performance information provided in this pre-market notification, the LuMend Percutaneous Catheter 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

JAN 1 6 2002

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

Re: K011562
LeMend Percuataneous Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous catheter.
Regulatory Class: Class II
Product Code: DQY
Dated: October 18, 2001
Received: October 18, 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,

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): ~~TBD~~ K011562

Device Name: **LuMend Percutaneous Catheter**

Indications For Use:

The LuMend Percutaneous Catheter is intended to be used in conjunction with a steerable guide wire in order to access discreet regions of the coronary vasculature. It may be used to facilitate placement of guide wires and other interventional devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011562

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

(Optional Format 1-2-96)