APR 2 3 2004

K040771

3. 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: March 24, 2004

Name: LuMend, Inc.
Address: 400 Chesapeake Drive
Redwood, CA. 94063
Office: 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
Trade Name: Outback® Catheter
Common Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Devices:

The Outback® Catheter is substantially equivalent in intended use and method of operation to the following predicate devices:

LuMend Outback® Catheter cleared via 510(k) K032298 on 8/26/04

Device Description:

The Outback® catheter is a sterile, single use device comprised of three primary elements. 1) guide tip, [deployment shaft], 2) catheter shaft and 3) deployment handle with a control knob. Upon proximal retraction of the guide via the control knob, the guide's curved tip is positioned coaxially within the nosecone. In this configuration the catheter may be tracked over a guide wire to the selected vascular site. The guidewire is then retracted into the guide, allowing the curved guide tip to be advanced from the nosecone end port. The radiopaque nosecone and guide tip facilitate placement into the selected region of the vascular site, with fluoroscopic guidance. Upon proper placement of the guide tip, the guide wire may be advanced through the guide and

into the desired location. The guide tip is then retraced into the nosecone, and the catheter is proximally retraced leaving the guide wire in place in the vasculature.

Intended Use:

The Outback® Catheter is intended to facilitate placement and positioning of guidewires/catheters within the peripheral vasculature. The Outback® Catheter is not intended for use in the coronary or cerebral vasculature.

Comparison to Predicate Device(s):

The LuMend Outback® Catheter is very similar to the previously cleared LuMend Outback® Catheter cleared via 510(k) K032298. A few minor changes have been made (see detailed device description), however, the principle of operation, intended use, fundamental design, and function of the product remains basically the same. Additional material options have been added. This version of the Outback® Catheter is clearly substantially equivalent to the previously cleared Outback device.

Summary:

Based upon the indication for use and the design and engineering data provided in this pre-market notification, the Outback® 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

APR 2 3 2004

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

Re: K040771
Trade Name: Outback® Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: March 24, 2004
Received: March 25, 2004

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) 594-4646. 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,

Donna R. Vochmer

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

Enclosure

Indications for Use

510(k) Number (if known): K040771

Device Name: Outback® Catheter

Indications For Use:

The Outback® Catheter is intended to facilitate placement and positioning of guidewires/catheters within the peripheral vasculature. The Outback Catheter is not intended for use in the coronary or cerebral vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachner

(Division Sign-Off)

Cardiovascular Devices

510(k) Number K040771