K032298

AUG 2 6 2003

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

Applicant Information:

Date Prepared:	July 23, 2003
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:

Abbott Laboratories Outback® Catheter (K001577)
Abbott Laboratories Outback® Catheter (K014117)

Device Description:

The Outback catheter is comprised of four primary elements: 1) guide 2) catheter shaft 3) rotating hemostasis valve (RHV) and 4) deployment handle or control knob. The guide is a single-lumen, steel braided polyimide shaft that can be extended or retracted by the control knob. The tubular catheter shaft houses this guide and is also steel braided polyimide in composition. The rotating hemostasis valve (RHV) has two functions: a one way valve allows for flushing of the catheter while a locking hub at the proximal end of the RHV controls the retracted position of the guide.

The fourth component is the deployment handle/control knob that is used to extend or retract the guide. This control knob also functions as a port with a luer fitting for flushing of the guide wire lumen.

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 essentially identical to the Abbott Laboratories Outback® Catheter (K014117). This Abbott device was originally cleared via 510(k) K001577. After LuMend's reacquisition of the Outback® Catheter from Abbott, a few minor changes have been made (see detailed device description below). However, the principle of operation, intended use, design, materials, and function of the product remains virtually unchanged. This version of the Outback® Catheter is clearly substantially equivalent to the aforementioned predicate devices.

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

AUG 2 6 2003

LuMend, Inc.
c/o Mr. Michael A. Daniel
400 Chesapeake Drive
Redwood, CA 94063

Re: K032298
Outback® Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 23, 2003
Received: July 25, 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.

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,

Brian 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 K032298

Device Name: Outback® Catheter

Indications For Use:

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

(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 K032298

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

(Optional Format 1-2-96)