**LUTHER MEDICAL PRODUCTS, INC.**
14332 CHAMBERS ROAD
TUSTIN, CALIFORNIA 92780-6912

(714) 544-3002
FAX (714) 544-7273

K974543

FEB 10 1998

## GENERAL INFORMATION:

| | |
|---|---|
| Applicant's Name and Address | Luther Medical Products, Inc.<br>14332 Chambers Road<br>Tustin, CA 92780-6912<br>Phone: (714) 544-3002<br>FAX: (714) 544-7273 |
| Contact Person: | Barbara C. Luther<br>Voice Mail: (714) 544-3002 Ext. 227<br>Phone: (714) 646-5183<br>FAX: (714) 650-1492 |
| Date of Summary: | August 24, 1997 |
| Common/Usual Name: | Catheter Guide Wire Kit |
| Proprietary Name: | L-Cath® Modified Seldinger Technique (MST) Kit |
| Classification Name: | Catheter Guide Wire, Kit<br>Classification Number: 79KGZ<br>Class II<br>§848.4200 |

## COMPARISON TO LEGALLY MARKETED DEVICES:

Arrow, International
HDC, Corporation
Cook Critical Care

## DEVICE DESCRIPTION:

The L-Cath Modified Seldinger Technique Kit consists of over-the-needle insertion catheters, a scalpel, measuring tape, sterile drapes, scissors, needle holder, syringe, with a sheath dilator and guide wire, in appropriate sizes to accommodate the Luther Medical line of Peripherally Inserted Catheters, the "parent devices". Included in the kit are appropriate accessories to aid in this technique.

SUMMARY: The contents of the kit are either similar or identical to those devices, with the same intended use, on the market. Luther Medical has smaller neonate/pediatric tubing then the competitors and therefore requires a special guide wire OD to accommodate these catheters. A detail comparison is found on the last page of this summary.

SUBSTANTIAL EQUIVALENCE: The guide wire insertion and/or exchange technique has been available to the medical community for over 17 years. The .018" guide wire is too large for the Luther line of catheters specifically used in pediatric and neonatal care.

Testing of the OD of the guide wire through the ID of existing Luther Medical catheters has proven to be accurate and appropriate for this application.

Biocompatibility testing was completed on the guide wire of similar size in another 510(k) for Silicone catheters.

POTENTIAL COMPLICATIONS: Extensive studies are available in the scientific literature to address the known complications from an insertion, or exchange, of catheters using the modified Seldinger technique. They include but are not limited to:

| | | |
|---|---|---|
| Infection | Discomfort | Arrythmias |
| Damage to the Intima of the Vein | Air Emboli | Catheter Emboli |
| Veno Spasm | Difficulty Threading Catheter | Difficulty Removing Guide Wire |
| Arterial Placement | Bleeding from Site. | Thrombosis |

CONCLUSION: Based on the evidence presented the devices are either essentially similar/or identical materials.

The intended use is the same and therefore the devices are considered substantially equivalent.

**Components of Luther Medical Products, Inc. MST Kits**
**and**
**Companies w/ Legally Marketed MST Kit Devices**

| Contents in MST KIT | Luther Medical Products, Inc. | Arrow International | HDC | Cook Critical Care |
|---|---|---|---|---|
| Wire Guide Diameter in inches | .018" x 45 , 50, 60, 80 cm<br>.012" X 45, 50 cm<br>.010" X 45 cm | .018" X 25 , 33 ,85 cm<br>.025" X 25, 68 cm<br>.035" X 45, 60, 68 cm | .018" X 80 cm | .018" X 50 cm<br>.021" X 60 cm<br>.025" X 60 cm |
| Scalpel | Yes | Yes | Yes | Yes |
| Intravenous OTN Introducer/Catheter | 20 ga. X 2"<br>22 ga. X 1"<br>24 ga. X ¾" | No | No | 25 ga.<br>22 ga. |
| Hypodermic Needle | 22 ga. X 1" | No | No | No |
| Syringe | 5cc | Yes | Yes | Yes |
| Introducer Needle | 21 X 2.75" w/echogenic tip | | 21 ga w/echogenic tip | 3.5 Fr.<br>4.0 Fr.<br>4.5 Fr.<br>5.0 Fr. |
| Measuring Tape | Yes | Yes | Yes | Yes |
| Iris scissor | Yes | No | No | No |
| Catheter Clamp/Needle Holder | Yes | Yes | No | Yes |
| Sheath/Dilator | 3, 4, & 5 Fr. | 5, 5.5, & 7 Fr. | 5 Fr. | 4 Fr.<br>5 Fr.<br>7 Fr. |
| Sterile Drape | Yes | Yes | No | No |
| MST Introducer Kit | All of the above.<br><br>Catheters and Procedural items are provided separately as L-Cath, Single and DuaL-Cath PICC Catheters. | All of the above plus catheters and procedural accessories and drugs. | One 21 ga introducer needle with echogenic tip, One 0.18" floppy guide wire (80cm) and One Sheath/Dilator assembly | All of the above plus catheters and procedural accessories and drugs. |
| Labeling and Directions for Use | Available Upon Request | Submitted w/510(k) | Submitted w/510(k) | Submitted w/510(k) |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Barbara C. Luther
Regulatory Affairs
Luther Medical Products, Incorporated
530 Kings Road
Newport Beach, California 92663-5710

FEB 10 1998

Re: K974543
Trade Name: L-CATH Modified Seldinger Technique Insertion/Catheter Exchange Kit
Regulatory Class: II
Product Code: FOZ
Dated: August 4, 1997
Received: December 3, 1997

Dear Ms. Luther:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the L-Cath Modified Seldinger Technique Insertion/Catheter Exchange Kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your L-CATH Modified Seldinger Technique Insertion/Catheter Exchange Kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number:** K974543

**Device Name:** **L-CATH MODIFIED SELDINGER TECHNIQUE INSERTION/CATHETER EXCHANGE KIT**

**INDICATIONS FOR USE:**

**"Statement of Indications for Use"**

The L-Cath Modified Seldinger Technique Accessory Kit is designed for placement and/or exchange of the L-Cath Peripherally Inserted Catheter System in 16 ga. (5Fr.), 18 ga. (4Fr.), 20 ga. (3Fr.), 24 ga. (2.6 Fr.) and the L-Cath Dual Lumen 16 and 18 ga.

Utilization of a Modified Seldinger Technique for catheter placement has been demonstrated to be effective for the placement of peripherally inserted central catheters in patients, **pediatric** and adult, with difficult to access veins.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974543

X Prescription Use