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K980090

MAR 24 1998

510(k) SUMMARY

GENERAL INFORMATION:

Applicant's Name and Address	Luther Medical Products, Inc. 14332 Chambers Road Tustin, CA 92780-6912 Phone: (714) 544-3002 FAX: (714) 544-7273
Contact Person:	George Brdlik Voice Mail: (714) 544-3002 Ext. 224 FAX: (714) 544-7273
Date of Summary:	September 4, 1997
Common/Usual Name:	Peripherally Inserted Catheter
Proprietary Name:	ONECATH® Catheter System an L-Cath®
Classification Name:	Catheter, Intravascular, Long Term 80FOZ Classification Number: ξ880.5200 Class II Catheter, Long Term, Implanted 80LJS Classification Number: None Class II

COMPARISON TO A LEGALLY MARKETED DEVICE:

ONECATH (K930743)

DEVICE DESCRIPTION:

The ONECATH Catheter System consists of a SafeSide II® introducer and a radiopaque single lumen polyurethane catheter with a clear tip. The SafeSideII introducer consists of a stainless steel needle and a two-part locking needle protection device with a flashback chamber and introducer protector. The 60, 50 and 20 cm catheters are marked in 5cm increments, in a linear tear protective sleeve. For the

60, 50 and 20 cm catheters a stylet is pre-inserted through the Y-site injection port that is connected to the catheter. A vent plug is inserted in the side port of the Y-site. The SafeSide II introducer is pre-inserted in the catheter through an aperture approximately 2cm from the tip. The ONECATH catheter system is available in various lengths of 60, 50 and 20 cm and is packaged in a two-part tray in a pouch. The ONECATH 5cm catheter is packaged in a pouch with a hemostasis valve. The product contains no DEHP or latex. The female luer is lipid resistant. Non-serrated forceps are included.

SUMMARY:

The basic device is essentially the same as the original ONECATH with a minor change in tip configuration. There is no change in intended use.

SUBSTANTIAL EQUIVALENCE: The ONECATH has been marketed since 1994 with no reported adverse effects.

The modification poses no additional risks or potential questions of efficacy.

The results of use of this catheter system indicates that it is acceptable for human implant.

Based on the proposed modification and the device similarity to the original in material, design and intended use the device is considered to be substantially equivalent.

POTENTIAL COMPLICATIONS: Extensive studies are available in the scientific literature to address the known complications from the insertion of catheters. The types and causes of safety and/or effectiveness problems that have been reported in use of infusion catheters are well known.

The potential exists for serious complications, some of which are as follows:

AIR EMBOLUS
ARRHYTHMIA

HYDROTHORAX
INFECTION AND
CATHETER RELATED
SEPSIS

POTENTIAL COMPLICATIONS:

ARTERIAL PUNCTURE	IMPLANT REJECTION
BLEEDING	MIGRATION OF CATHETER
CARDIAC TAMPONADE	MYOCARDIAL DAMAGE
CATHETER FRAGMENT	NERVE DAMAGE
EMBOLUS	
CATHETER	PHLEBITIS, CHEMICAL
OCCLUSION	AND MECHANICAL
DAMAGE TO	PNEUMOTHORAX
CATHETER	
DRUG	PULMONARY ARTERY
EXTRAVASATION	RUPTURE
EROSION/PERFORATIO	THROMBOEMBOLISM
N OF VESSEL/HEART	
HEMATOMA	THROMBOSIS
HEMOTHORAX	VALVULAR DAMAGE
	ALONG VEIN

CONCLUSION:

Based on the evidence presented the device is manufactured using essentially the same materials.

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

A comparison of the subject device to the claimed device follows on the next page.

Element of Comparison	Subject Device Modified ONECATH	Claimed Device Legally Marketed ONECATH K930473
Catheter Type FOZ – Intravascular Catheter And LJS - Long-term Intravascular Catheter Intended Use	Long-Term Intravascular Catheter, Adult and Neonate/Pediatric Peripheral, Midline, Midclavicular and CVC (PICC) I.V. Administration Blood Therapy Blood Sampling	Long-Term Intravascular Catheter, Adult and Neonate/Pediatric Peripheral, Midline, Midclavicular and CVC (PICC) I.V. Administration Blood Therapy Blood Sampling
Mode of Operation	Catheter Insertion Over the Needle Introducer with protected needle. Recommended Site, Anticubital Peripheral Vein. Additional site <i>selection may be at the direction of the practitioner when used on the neonatal and pediatric population.</i>	Catheter Insertion Over the Needle Introducer with protected needle. Recommended Site, Anticubital Peripheral Vein. Additional site <i>selection may be at the direction of the practitioner when used on the neonatal and pediatric population.</i>
Intended Anatomical Location of Distal End	Peripheral – Distal portion of the extremity Midline –Proximal portion of the extremity Midclavicular – Proximal axillary or subclavian veins. Central – (PICC) within the Superior Vena Cava This is not a Right Atrium Catheter	Peripheral – Distal portion of the extremity Midline –Proximal portion of the extremity Midclavicular – Proximal axillary or subclavian veins. Central – (PICC) Superior Vena Cava This is not a Right Atrium Catheter
Cannula Introducer	Stainless Steel Over the Needle	Stainless Steel Over the Needle
Catheter Markings	5 cm intervals from distal end of strain relief.	5 cm intervals from distal end of strain relief.
Catheter Material	Radiopaque Polyurethane	Radiopaque Polyurethane
Distal End Configuration	Tapered on Over the Needle Cannula Introducer	Tapered on Over the Needle Cannula Introducer
Proximal End Configuration	Strain relief, standard luer lock, with pre-inserted stylet through a Y-site.	Strain relief, standard luer lock, with pre-inserted stylet through a Y-site.
Catheter Gauge Size	16, 18, 20, 22	16, 18, 20, 24
Catheter Length	5 – 60 cm	10 – 60 cm



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 1998

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

Re: K980090
Trade Name: Onecath®, L-Cath Catheter System, Model OC-
(16-22 ga., 5cm - 60 cm)
Regulatory Class: Unclassified
Product Code: LJS
Dated: January 4, 1998
Received: January 9 1998

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. 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 (Pre-market 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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

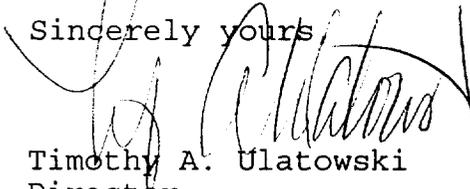
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 "<http://www.fda.gov/cdrh/dsmamain.html>".

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 : K980090

Name of Device: **ONECATH CATHETER SYSTEM PERIPHERALLY INSERTED CATHETERS**

INDICATIONS FOR USE:

“Statement of Indications for Use”

The ONECATH Catheter System is designed for use when patient therapy requires repeated venous access or prolonged intravenous administration of fluids, medications, and/or nutritional solutions as prescribed. The catheter is designed to be inserted in a peripheral vein. While any vessel suitable for insertion may be used; the basilic vein is the most commonly used vein.

Note: This product may be used in pediatric as well as adult patients. Vascular cannulation is an important Procedure in the management of ill infants and children. The indications for use in children are the same as adults; however, insertion techniques are often modified according to the age and size of a child. If the practitioner is inexperienced in utilizing this product in a child, appropriate consultation should be sought.


(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980090

X Prescription Use