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Safety and Effectiveness Information

Submitted By: April Lavender, RAC
Vice President, Regulatory Affairs
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235

Date: July 1, 1998

Device:

Trade Name: Uldall Double Lumen Hemodialysis Catheter
Proposed Classification Name: Accessories, Blood Circuit, Hemodialysis (78KOC)

Predicate Devices:

The Uldall Double Lumen Hemodialysis Catheter, subject of this submission, is similar in terms of intended use, materials of construction and technological characteristics to predicate devices.

Device Description:

The Uldall Double Lumen Hemodialysis catheter is a silicone double lumen catheter to be used for blood withdrawal and infusion. The silicone material will be the same the material used for the commercially available Uldall Double Lumen Hemodialysis Catheter. The double lumen construction will allow for blood withdrawal through the distal port and blood infusion through the proximal port. The ports will be separated by cutting away 1 cm of the thin walled lumen. The catheter will have standard Luer lock fittings on the proximal end. Lumen volume information will be printed on the extension tubes of the manifold assembly. Tubing clamps will be placed on the extension tubes. A synthetic fiber cuff will be affixed to the catheter to allow for device fixation.

Substantial Equivalence:

The Uldall Double Lumen Hemodialysis Catheter, subject of this submission, is substantially

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equivalent to the commercially available Uldall Double Lumen Hemodialysis Catheter, D.C.#K923468 and the PermCath Dual Lumen Catheter, D.C.#K871749. The original Uldall Double Lumen Hemodialysis Catheter is being marketed by COOK INCORPORATED today. It is manufactured with double lumen silicone tubing measuring 16.0 Fr. in outside diameter and 26, 28, 30 and 32 cm lengths. The Uldall Double Lumen Hemodialysis Catheter, subject of this submission, will be manufactured with double lumen silicone tubing measuring 11.0 Fr. in outside diameter and 18 cm length.

Test Data

The catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of the following.

- ❑ Pull Testing - Cuff Adhesion to Catheter Shaft
- ❑ Pull Testing - Fitting/Extension Tube Junction
- ❑ Pull Testing - Tunneler
- ❑ Lumen Volume

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as hemodialysis catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Ms. April Lavender, RAC
Vice President Regulatory Affairs
COOK®, Inc.
925 South Curry Pike
P.O. Box 489
Bloomington, Indiana 47402

Re: K982333
Uldall Double Lumen Hemodialysis Catheter (11.0 Fr.)
Regulatory Class: III
21 CFR 876.5540/Product Code: 78 MSD
Dated: November 13, 1998
Received: November 16, 1998

Dear Ms. Lavender:

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 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). 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 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 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4616. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT. Daniel G. Schultz, M.D.
Acting Director
Division of Reproductive, Abdominal,
Ear, Nose and Throat, and
Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K982333

Device Name: Uldall Double Lumen Hemodialysis Catheter (11.0 Fr.)

Indications For Use: The Uldall Double Lumen Hemodialysis Catheter is designed for short or long-term hemodialysis access in the presence of renal failure. Percutaneously placed double lumen catheter is intended for blood infusion and withdrawal. This device and components of the tray are supplied sterile and intended for single-use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over the Counter Use____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982333 | S001