

Safety and Effectiveness Information

K 992198

Submitted By: Lisa Webb, RAC
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235
June 29, 1999

Device: Trade Name: Urethane PICC Line

Proposed Classification Name: Intravascular Catheter

Predicate Devices:

The Urethane PICC Line is similar in terms of intended use, materials of construction, and technological characteristics as the predicate devices reviewed: COOK® Silicone PICC Lines, Arrow International PICC Lines, and Vaxcel™ PICC Lines.

Device Description:

The Urethane PICC Line is comprised of five components which can be further described as follows:

- Catheter: The catheter is constructed of polyurethane and is available in 4 Fr and 5 Fr single lumen configurations. The catheter is 60 cm in length.
 - The distal end of the catheter tubing has depth distance markers in 5 cm increments. The final 5 cm (from the 55 cm mark to the winged manifold) are designed as a bump tubing.
 - The proximal end configuration is composed of a winged manifold, extension tubing, and a luer lock hub which are discussed below.
- Winged Manifold: The winged manifold is constructed of polyurethane.
- Extension Tubing: The extension tube is constructed of polyurethane.
- Clamp: A plastic clamp is provided around the external surface of the extension tube.
- Luer Lock Hub: The luer lock hub is constructed of polyurethane and is stamped on either side with the following information: 1) COOK® 4 FR/.9 CC LUM VOL, or 2) COOK® 5 FR/1.3 CC LUM VOL.

The Urethane PICC Line will also be available in a set or tray that incorporates legally marketed accessories. These accessories are identical to those currently sold in COOK®'s Silicone PICC Line sets and trays.

Substantial Equivalence:

Three devices are currently marketed which are believed to be substantially equivalent to the Urethane PICC Line, subject of this submission. These devices include Silicone PICC Lines (COOK® Inc.), Peripherally Inserted Central Catheters (Arrow International), and Vaxcel™ PICC Lines (Boston Scientific/Medi-Tech®).

Silicone PICC Lines (COOK® Inc.) are legally marketed as Preamendment Devices under the document registration number A137605 and have not been the subject of premarket notification clearance. These Silicone PICC Lines are indicated for intravenous administration of nutrient fluids, chemotherapeutic agents and other drugs for therapy. The device is constructed of silicone and is manufactured in single and double lumen configuration. The catheter is available in sizes of 3 Fr, 4 Fr, 5 Fr, 6 Fr, and 7 Fr and in lengths ranging from 50 to 60 cm.

Peripherally Inserted Central Catheters (Arrow International) were reviewed as substantially equivalent under K862056 and are indicated for venous access to the central circulation through a peripheral vein for an alternative method of intravenous therapy for select adult and pediatric patients. The device is constructed of Urethane and is manufactured in single or double lumen configurations. The catheter is available in sizes of 16 gage, 3 Fr, 4 Fr, and 5 Fr and in lengths ranging from 50 to 70 cm.

Vaxcel™ PICC Lines (Boston Scientific/Medi-Tech®) are currently in commercial distribution. The Vaxcel™ PICC Lines are indicated for use when central venous catheterization or prolonged intravenous administration of fluids, medications, and/or nutritional therapy is prescribed. The device is constructed of Urethane and is manufactured in single or double lumen configurations. The catheter is available in sizes of 4 Fr and 5 Fr and in a length of 60 cm.

The Urethane PICC Lines will be indicated for intravenous administration of nutrient fluids, chemotherapeutic agents and other drugs for therapy. The device will be constructed of polyurethane and will be manufactured in a single lumen configuration. The catheter will be available in sizes of 4 Fr and 5 Fr and in a length of 60 cm. The fundamental scientific technology of the modified device has not been changed by the requested modifications of this submission.

Test Data

The Urethane PICC Line has been subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

- Tensile testing of junctions
- Flow testing
- Burst testing
- Leakage testing
- Air leakage during aspiration
- Hub durability
- Extension Tube Durability
- Stability Testing



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1999

Ms. Lisa Webb
Regulatory Affairs Coordinator
Cook®, Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, Indiana 47402

Re: K992198
Trade Name: Urethane PICC Line Model UPICS-
Regulatory Class: II
Product Code: FOZ
Dated: August 5, 1999
Received: August 6, 1999

Dear Ms. Webb

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 (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, 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 premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

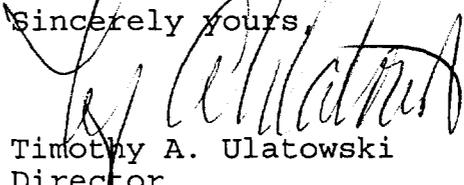
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

Special 510(k) Premarket Notification: Modified Device
Urethane PICC Line
COOK INCORPORATED

510(k) Number (if known): K992198

Device Name: Urethane PICC Line

Indications for Use:

Used for venous pressure monitoring, blood sampling and administration of drugs and fluids.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
Use _____
(Per 21 CFR 801.109)

OR Over-the-Counter

Patricia Cicceri
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K992198