DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 15, 2014

Cook Incorporated
Jennifer Richardson
Regulatory Affairs Team Lead
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402-0489

Re: K140085
Trade/Device Name: Universa® Loop Drainage Catheter Set
Universa® Malecot Drainage Catheter Set
Regulation Number: 21 CFR 876.5090
Regulation Name: Suprapubic urological catheter and accessories
Regulatory Class: Class II
Product Codes: FEW, KOB, LJE
Dated: October 24, 2014
Received: October 27, 2014

Dear Jennifer Richardson,

This letter corrects our substantially equivalent letter of November 18, 2014.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140085

Device Name
Universa® Loop Drainage Catheter Set
Universa® Malecot Drainage Catheter Set

Indications for Use *(Describe)*
The Universa® Loop Drainage Catheter Set is intended to provide percutaneous urine drainage from the genitourinary system.

The Universa® Malecot Drainage Catheter Set is intended to provide percutaneous urine drainage from the genitourinary system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(k) Summary

Cook Incorporated
Universa® Loop Drainage Catheter Set and Universa® Malecot Drainage Catheter Set
510(k) Summary
21 CFR 807.92

Submitted By:

Applicant:	Cook Incorporated
Address:	750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Phone Number:	(800) 468-1379
Fax Number:	(812) 332-0281
Contact:	Jennifer Richardson
Contact Address:	Cook Incorporated 750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Contact Phone Number:	800-346-2686 or 812-335-3575 ext 2370
Contact Fax Number:	812-332-0281
Date Prepared:	24 October 2014

Device Information:

Trade name:	Universa® Loop Drainage Catheter Set Universa® Malecot Drainage Catheter Set
Common name:	Percutaneous Drainage Catheter
Classification:	Class II, Unclassified
Regulation:	21 CFR §876.5090
Product Code:	FEW, KOB, LJE

Predicate Devices:

Percutaneous Drainage Loop Catheter Sets

K931195, December 22, 1993

Vance Percutaneous Malecot Nephrostomy Catheter Set

K810368, March 20, 1981

Indications for Use:

The Universa® Loop Drainage Catheter Set is intended to provide percutaneous urine drainage from the genitourinary system.

The Universa® Malecot Drainage Catheter Set is intended to provide percutaneous urine drainage from the genitourinary system.

Device Description:

The Universa® Percutaneous Drainage Catheter Sets include introductory and exchange sets available with either a loop (6-14 Fr) or a Malecot catheter (8-24 Fr). Suprapubic sets are available with a Malecot catheter (8-16 Fr). Each set includes a drainage catheter and connecting tube, and may also include straightening stylets, trocar needle with obturator, hollow needle, wire guide, dilators, silicone retention disc with pull tie, or one-way stopcock. The devices will be supplied sterile and intended for one-time use.

Comparison to Predicate Device:

The following table presents the main technological similarities and differences between the predicate and proposed devices.

	Vance Percutaneous Malecot Nephrostomy Catheter Set K810368	**Percutaneous Drainage Loop Catheter Sets K931195**	**Universa Percutaneous Drainage Catheter Sets Subject of This Submission**
Set components	Drainage catheter (Malecot configuration) Two-part trocar needle Wire guide Dilators Connecting tube	Drainage catheter (loop configuration) Two-part trocar needle Wire guide Dilators Connecting tube	Includes: Drainage catheter (loop or Malecot tip configuration) Connecting tube May also include: Straightening stylets Two-part trocar needle Hollow needle Wire guide Dilators Silicone retention disc with pull tie One-way stopcock
Catheter Size (Fr)	14	6 – 14	6 – 14 (loop), 8 – 24 (Malecot)
Catheter Length (cm)	30	12 – 30	15 – 30

The proposed devices are substantially equivalent to the predicate in terms of intended use, duration of use, principles of operation, and technological characteristics.

Discussion of Tests and Test Results:

The device was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

1. Tensile Strength – Testing shows the tensile force during proper clinical use should not fracture the catheter set materials and/or bonds. The predetermined acceptance criteria were met.
2. Loop and Malecot Retention – Testing shows that the loop and Malecot retention features of the catheters resist dislodgement or removal of the catheter. The predetermined acceptance criterion was met.
3. Gravity Flow Rate, Lumen Blockage, and Leakage Testing – Testing shows that water will consistently flow through the catheters without any blockage or leakage. The predetermined acceptance criteria were met.
4. Biocompatibility – Testing, in conformance with ISO 10993-1, shows the device is biocompatible. The predetermined acceptance criteria were met.
5. Simulated Use – Testing shows that the devices are compatible and perform according to the instructions for use. The results of the study are acceptable for clinical practice.

Conclusions Drawn from the Tests:

The results of these tests provide reasonable assurance that the device is as safe and effective as the predicate device and support a determination of substantial equivalence.