JAN 27 1999

510(k) Premarket Notification
Chait Cecostomy Catheter
COOK INCORPORATED

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
July 17, 1998

Device: Trade Name: Chait Cecostomy Catheter

Proposed Classification Name: Introduction, Drainage Catheter

Predicate Devices:

The Chait Cecostomy Catheter is similar in terms of intended use, materials of construction, and technological characteristics to the predicate devices reviewed, the Ultrathane™ Biliary Drainage catheter with a COOK-Cope Type Loop and the Ultrathane™ Nephrostomy Catheter with a COOK-Cope Type Loop.

Device Description

The Chait Cecostomy Catheter is a "trap door", low profile catheter which facilitates antegrade colonic flushing. The device is supplied sterile and is intended for one time use. A tract must be established through the abdomen into the cecum prior to placement of the trap door catheter. Accessories used in conjunction with this device include, but are not limited to, a metal stiffener, a wire guide, a connecting tube, a syringe and saline solution.

The device consists of a cecostomy catheter with a trap door attachment and an access adapter. The 10.2 French catheter is made of urethane and is manufactured with five (total) pigtail curves. The distal end of the catheter includes three sideports which are evenly spaced inside the fifth curve. The endhole is 0.038 inches in diameter. The total length of the catheter is 20cm.

The trap door fitting is also made of urethane and lies flat against the abdomen wall. It incorporates a plastic plug which locks securely into place when the catheter is not being accessed.

The access adapter is a metal cannula. The distal end of the cannula is curved and can be

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attached to the trap door fitting as needed to flush fluids through the Chait Cecostomy Catheter and into the cecum. The proximal end of the cannula is designed with a large tapered fitting that will fit most taper tip syringes.

Substantial Equivalence

COOK INCORPORATED currently markets two devices, the Ultrathane™ Nephrostomy Catheter with a COOK-Cope Type Loop and the Ultrathane™ Biliary Drainage Catheter with a COOK-Cope Type Loop, which are believed to be substantially equivalent to the catheter, subject of this submission. The Ultrathane Biliary Drainage Catheter is indicated for antegrade biliary drainage. The Ultrathane™ Nephrostomy Catheter is indicated for external urine drainage from the renal pelvis. Both devices are manufactured in either Ultrathane™ or polyurethane. These devices are classified as modified Preamendment devices and were also reviewed as substantially equivalent under K851242.

The Ultrathane™ Biliary Drainage Catheter is manufactured with a single lumen polyurethane tubing measuring 8.5, 10.2, 12.0, and 14.0 Fr. in outside diameter in a nominal 40cm length. The Ultrathane™ Nephrostomy Catheter is manufactured with a single lumen polyurethane tubing measuring 8.5, 10.2, 12.0, and 14.0 Fr. in outside diameter in a nominal 25cm length. The Chait Cecostomy Catheter will be manufactured with a single lumen urethane tubing measuring 10.2 Fr. in outside diameter and 20cm in length.

Test Data

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

- Clinical Trials
- Tensile Strength Tests
- Biocompatibility Tests

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 a catheter which facilitates antegrade colonic flushing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1999

COOK INCORPORATED
c/o Ms. April Lavender, RAC
Vice President Regulatory Affairs
925 South Curry Pike
P.O Box 489
Bloomington, Indiana 47402

Re: K982500
Chait Cecostomy Catheter Set
Dated: October 28, 1998
Received: October 29, 1998
Regulatory Class: II
21 CFR 876.5980/Procode: 78 KNT
21 CFR 876.5895/Procode: 78 EXD

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. 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 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, 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 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) 594-4613. 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

COOK INCORPORATED
Response to Request for Additional Information
K982500 Chait Cecostomy Catheter

510(k) Number (if known): K982500

Device Name: Chait Cecostomy Catheter

Indications for Use:

The Chait Cecostomy Catheter is used to instill fluids through a cecostomy into the colon to promote evacuation of the contents of the lower bowel through the anal opening and is intended to be an aid in the management of fecal incontinence. The catheter is placed and maintained in a percutaneously prepared opening such as a cecostomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982500/S001