K043203 pg 1 of 1



MAY 1 1 2005



# 510(K) SUMMARY

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|---|---|
| **SPONSOR:** | Wilson-Cook Medical<br>4900 Bethania Station Road<br>Winston-Salem, NC 27105 |
| **CONTACT/SUBMITTER:** | Marge Walls-Walker<br>Regulatory Affairs Specialist<br>800-245-4707 |
| **DATE OF SUBMISSION:** | November 15, 2004 |
| **DEVICE:**<br>Trade Name(s): | Nasal Jejunal Feeding Tube, Nasal Jejunal Feeding Tube w/Flaps, Cook Inc. "Tiger Tube"™ |
| Common Name: | Nasal Jejunal Feeding Tube, Enteral Feeding Tube |
| Classification: | 21 CFR § 876.5980. 78 KNT |
| **PREDICATE DEVICES:** | Wilson-Cook Enteral Feeding Tube (K 874393) |
| **INTENDED USE:** | This device is intended to provide short-term enteral access for delivery of nutrition and/or medications to the small bowel.<br>The device is supplied sterile and is intended for single use only. |
| **DEVICE DESCRIPTION:** | The proposed Nasal Jejunal Feeding Tube is a single lumen, radiopaque PVC tube. The 8Fr and 10Fr diameter tubes are intended to be introduced endoscopically and are supplied with a wire guide. The 14FR tube with flaps is intended to be introduced manually in conjunction with peristalsis into the jejunum. The distal portions of all tubes have feed ports for delivery of liquid nutrition and/or medication. All tube kits include a nasal transfer tube and feeding adapters. |
| **COMPARISON OF CHARACTERISITICS:** | We believe the proposed device to be substantially equivalent to the currently marketed Wilson Cook Nasal Jejunal Feeding Tubes with respect to Intended Use, Indications for Use and Technological Characteristics |
| **PERFORMANCE DATA:** | We believe the proposed device to be substantially equivalent to the named predicate based on performance characteristics tested. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1 2005

Ms. Marge Walls-Walker
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K043203
Trade/Device Name: Wilson-Cook Nasal Jejunal Feeding Tubes and Nasal Jejunal Feeding Tube with Flaps
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: March 31, 2005
Received: April 4, 2005

Dear Ms. Walls-Walker:

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). 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 (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 (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 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, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K043203

**Device Name:** Wilson-Cook Nasal Jejunal Feeding Tubes and Nasal Jejunal Feeding Tube with Flaps

**Indications for Use:**

The Wilson-Cook Nasal Jejunal Feeding Tube and Nasal Jejunal Feeding Tube with Flaps are intended to provide short-term enteral access for delivery of nutrition and/or medications to the small bowel.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only ✓ OR Over-the-Counter_____
(Per 21 CFR § 801.109

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043203