**RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR**

## I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 20 1998

**Submitted By:**
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

**Device Description:**
The Wilson-Cook 10 Shot Multi-Band Ligator consists of a friction fit adapter for attachment to the distal tip of an endoscope, a barrel preloaded with ten (10) ligation bands, a trigger cord and handle for band deployment, an irrigation adapter and a loading catheter. This device is designed for attachment to the end of an endoscope for ligating esophageal varices or hemorrhoids. Once assembled and attached the endoscope is advanced to the desired banding site and individual bands are deployed via manipulation of the deployment handle and trigger cord. The multi-band feature allows for serial ligations, which reduces the need to remove the endoscope for reloading. This device is supplied non-sterile and is intended for single use only.

**Trade Name:** Wilson-Cook Ten Shot Multi-Band Ligator
**Common/Usual Name:** Band Ligator
**Classification Name/Code:** Ligator, Hemorrhodial, 78 FHN
Ligator, Esophageal 78 MND
**Classification:** FDA has classified similar devices as Class II, as per 21 CFR § 876.4400. This device falls within the purview of the Gastroenterology and Urology Device Panel.
**Performance Standards:** To the best of our knowledge, performance standards for this device do not exist.
**Intended Use:** Used to endoscopically ligate esophageal varices at or above the gastroesophagel junction or to ligate internal hemorrhoids.

**Predicate Device:**

| PREDICATE DEVICE | MANUFACTURER | DOCUMENT CONTROL NUMBER |
|---|---|---|
| Wilson-Cook Six Shot Multi-Band Ligator | Wilson-Cook Medical Inc. | K944220/A |

**Substantial Equivalence:**
The Wilson-Cook 10 Shot Multi-Band Ligator is substantially equivalent to the referenced predicate device with respect to design, materials of construction and intended use.

**RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR**

## I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

| DEVICE CHARACTERISTIC | Wilson-Cook 10 Shot Multi-Band Ligator [Subject of 510(K)] | Wilson-Cook Multi-Band Ligator (K944220/A) |
|---|---|---|
| **Intended Use** | Used to endoscopically ligate esophageal varices at or above the gastroesopahgeal junction or to ligate internal hemorrhoids. | Used to endoscopically ligate esophageal varices at or above the gastroesopahgeal junction or to ligate internal hemorrhoids. |
| **Components** | 1) Non-Patient Contacting Loading Catheter<br>2) Irrigation Adapter<br>3) Barrel with 10 Ligation Bands<br>4) Trigger Cord<br>5) Deployment Handle | 1) Non-Patient Contacting Loading Catheter<br>2) Irrigation Adapter<br>3) Barrel with 6 Ligation Bands<br>4) Trigger Cord<br>5) Deployment Handle |
| **Patient Contacting Materials** | **Friction Fit Adapter:** Polyurethane<br>**Barrel:** Polycarbonate<br>**Trigger Cord:** Vectran<br>**Bands:** Latex Rubber | **Friction Fit Adapter:** Polyurethane<br>**Barrel:** Polycarbonate<br>**Trigger Cord:** Vectran<br>**Bands:** Latex Rubber |
| **Method of Use** | Friction Fit adapter and barrel with ligation bands mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and deployment handle. | Friction Fit adapter and barrel with ligation bands mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and deployment handle. |
| **Bands** | Multiple bands can perform serial ligations without removal of the endoscope for reloading of bands. | Multiple bands can perform serial ligations without removal of the endoscope for reloading of bands. |
| **Sterility** | Non-Sterile, Disposable | Non-Sterile, Disposable |

**Testing:** Biocompatibility has been established for the patient contacting materials through a history of use in other similar medical devices and as applicable biocompatibility test results. This product line has been subjected to functional testing as appropriate for this modification. All results were comparable to results obtained for the predicate device hence establishing the safety and effectiveness for this product line extension.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1998

Ms. Paula Joyce
Regulatory Affairs Manager
Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K974018
Wilson-Cook 10 Shot Multi-band Ligator
Dated: October 17, 1997
Received: October 22, 1997
Regulatory Class: II
21 CFR 876.4400/Procode: 78 FHN, 78 MND

Dear Ms. Joyce:

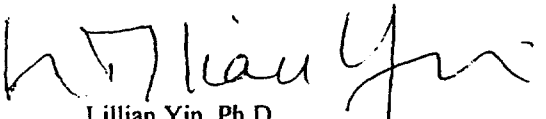
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Current Good Manufacturing Practice requirement, 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/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K974018



510(k) Number (if known): INITIAL 510(K) SUBMISSION UNKNOWN

Device Name: WILSON-COOK TEN SHOT MULTI-BAND LIGATOR

Indications For Use:

Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter D Nathan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974018

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)