K972647

P171

J. 510(k) SUMMARY

APR 10 1998

Submitted By:

Tammy Bacon
Cook Urological, Incorporated and Cook OB/GYN
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
July 14, 1997

Device:

Trade Name: CO_2 Pneumo-Dissector

Proposed Classification Name: Laparoscope, Gynecologic (And Accessories) 85 HET

Predicate Devices:

The CO_2 Pneumo-Dissector is substantially equivalent to predicate fluid dissectors in terms of indications for use, design, construction and materials equivalence. Specifically, this device is similar to the Pump Vac™ (Plus and III) with PAL™ (Probe for Aspiration/Lavage) manufactured by Marlow Surgical Technologies, Inc., 1810 Joseph Lloyd Parkway, Willoughby, OH 44094, the Nezhat-Dorsey Hydrodissection System manufactured by American Surgical Instruments, Inc., 901 E. Sample Road, Suite C, Pompano Beach, FL 33064, and the Cabot Irrigation/Aspiration System with Corson Hydrodissection Insert™ manufactured by Cabot Medical, 2021 Cabot Boulevard West, Langhorne, PA 19047.

Device Description:

The CO_2 Pneumo-Dissector is used to gently dissect planes of soft tissue using short, pressure regulated, trigger-controlled pulses of CO_2 gas. The device may be used in both open and laparoscopic procedures. The primary materials used in this device are stainless steel, acetal, polyvinylchloride. These materials are widely used in the medical field and biocompatibility is assured. Testing to evaluate performance characteristics showed the CO_2 Pneumo-Dissector to meet device specifications, and accomplish safe and effective blunt tissue dissection.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging similar to the devices currently marketed and distributed by Cook Urological, Incorporated and Cook OB/GYN. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 1998

Ms. Brenda Davis
Regulatory Affairs
Cook Urological, Inc.
1100 West Morgan Street
Spencer, IN 47460

Re: K972647
CO_2 Pneumo-Dissector
Dated: January 19, 1998
Received: January 20, 1998
Regulatory Class: II
21 CFR 884.1720/Procode: 85 HET

Dear Ms. Davis:

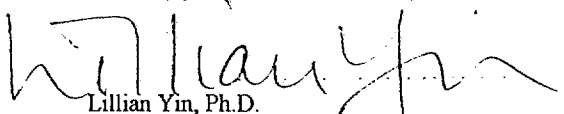
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K972647

Device Name: CO_2 Pneumo-Dissector

Indications for Use: The CO_2 Pneumo-Dissector is used to gently dissect planes of soft tissue using short, pressure regulated, trigger-controlled pulses of CO_2 gas. The device may be used in both open and laparoscopic procedures in which gentle, blunt dissection of soft tissue planes is desired.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972647

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