K980079

Attachment 14
510(k) Summary Statement for the
Coherent Tissue Morcellator Kit

APR - 9 1998

I. General Information

Submitter: Coherent Medical Group
3270 West Bayshore Road
Palo Alto, CA 94303

Contact Person: Anne C. Worden

Summary Preparation Date: January 8, 1998

II. Names

Device Names: Coherent Tissue Morcellator Kit

Primary Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

III. Predicate Devices

- Tissue Morcellator marketed by Cook Urological/Cook OB/GYN, Inc. (K925851 and K910939)
- Lasersonics Tissue Morcellator Set manufactured by Heraeus Surgical, Inc. (K935604)

IV. Product Description

The Coherent Tissue Morcellator Kit is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparoscopic, percutaneous, and open surgical procedures whenever access to the surgical site is limited.

Coherent Tissue Morcellator Kits are comprised of the following main components:
- a Morcellator handpiece;
- a variety of cutting blade sets;
- an aspiration pump;
- a variable speed control unit;
- a footswitch;
- a sterilization tray

The Coherent Morcellator Handpiece/Drive Units are provided as non-sterile, ready to be sterilized devices. The Cutting Blade Sets are provided either as sterile, single-use items, or as non-sterile, limited reuse, ready to be sterilized items. An optional sterilization tray may be used to sterilize the Morcellator Handpiece/Drive Units and the limited reuse cutting blade sets.

V. Indications for Use

The Coherent Tissue Morcellator Kit is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparoscopic, percutaneous, and open surgical procedures whenever access to the surgical site is limited.

VI. Rationale for Substantial Equivalence

The Coherent Tissue Morcellator Kit shares the same indications for use, and therefore is substantially equivalent to both the Tissue Morcellator marketed by Cook Urological/Cook OB/GYN, Inc. (K925851 and K910939) and the Lasersonics Tissue Morcellator Set manufactured by Heraeus Surgical, Inc. (K935604). In addition the Coherent Tissue Morcellator Kit shares similar design features, components and materials as the Tissue Morcellator marketed by Cook Urological/Cook OB/GYN, Inc. (K925851 and K910939).

VII. Safety and Effectiveness Information

Physical testing was conducted to demonstrate performance of the Coherent Tissue Morcellator Kit in accordance with product specifications. The component materials with expected and potential patient contact were tested to demonstrate acceptable biocompatibility. Cleaning and sterilization validation will be conducted prior to commercial distribution.

VIII. Conclusion

The Coherent Tissue Morcellator Kit was found to be substantially equivalent to the Tissue Morcellator marketed by Cook Urological/Cook OB/GYN, Inc. (K925851 and K910939) and to the Lasersonics Tissue Morcellator Set manufactured by Heraeus Surgical, Inc. (K935604). The Coherent Tissue Morcellator Kit shares the same indications for use as the predicate Cook and Lasersonics tissue morcellators. In addition, the Coherent Tissue Morcellator shares similar design features, and similar functional features as the currently marketed Cook Tissue Morcellator. Physical and biocompatibility test results demonstrated that the Coherent Tissue Morcellator Kit has acceptable performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Anne C. Worden
Senior Manager, Regulatory Affairs
Coherent Medical Group
3270 West Bayshore Road
Palo Alto, California 94303

APR - 9 1998

Re: K980079
Coherent Tissue Morcellator Kit
Regulatory Class: II
Product Code: GCJ
Dated: January 8, 1998
Received: January 9, 1998

Dear Ms. Worden:

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) 594-4595. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K990079

Device Name : **Coherent Tissue Morcellator Kit**

Indications For Use:

The Coherent Tissue Morcellator Kit is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparoscopic, percutaneous, and open surgical procedures whenever access to the surgical site is limited.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990079

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)