MAY 14 [illegible]

510(K) Summary

K990561

1. **Submitter Name, Address, and Date of Submission.**

Elizabeth Lazaro
Pilling Weck Surgical
420 Delaware Drive
Fort Washington, PA 19034
Telephone Number (800) 523-6507
Fax (215) 643-7930
Contact: Same as above.

2. **Name of the Device, Common, Proprietary (if known), and Classification.**
Classification Name: Biopsy Forcep and Telescope
Common Name: Optical Forcep
Proprietary Name: Pilling Weck Surgical Optical Forcep

3. **Identification of the legally marketed device to which the submitter claims equivalence.**
Pilling Weck Surgical Optical Forcep is substantially equivalent to Storz Vocal Cord Stripping Instrument

4. **Description of the Device.**
The Optical Forcep consists of two components
   a. Telescope
   b. Biopsy Forcep

5. **Intended Use of the Device.**
The Optical Forcep is to be used for Tracheobronchial or Esophageal foreign body removal or biopsy procedures.

6. **Summary of Technological Characteristics.**
The technological characteristics are the same as, or equivalent to, predicate devices by Storz Vocal Cord Stripping Instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 1999

Ms. Elizabeth Lazaro
Regulatory Affairs Associate
Pilling Weck Surgical
420 Delaware Drive
Fort Washington, Pennsylvania 19034

Re: K990561
Trade Name: Optical Forcep
Regulatory Class: II
Product Code: JEK, EOX, and EWY
Dated: February 17, 1999
Received: February 22, 1999

Dear Ms. Lazaro:

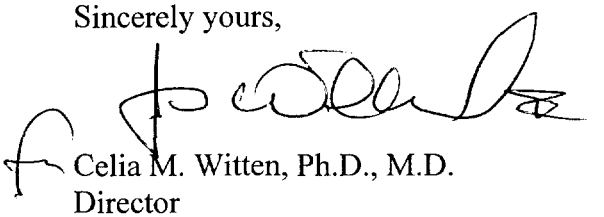
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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

510(K) Number (if known): K990561

Device Name: Pilling Weck Surgical Optical Forcep

Indications for Use:

To be used for Tracheobronchial or Esophageal foreign body removal or biopsy procedures. To be used through rigid scopes: Bronchoscopes, Esophagoscopic, Laryngoscopes and Mediastinoscopes

(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 K990561

Prescription Use X or Over-The-Counter Use _____

(Per 21 CFR 801.1 09)