OCT 13 1999

K991563

510(k) Summary / Statement

Submitters Name: **HENKE- SASS, WOLF of America, Inc.**
Soroco Industrial Part, Rte. 131
529 Ashland Avenue
Southbridge, MA 01550
Ph: 508-764-3200 Fax: 508-764-8242

Contact Name: Ellen Henke, Official Correspondent for Submission
Wayne Knupp, Jr., Director Sales & Marketing-HENKE SASS WOLF

Name of Device: Hysteroscopic Resectoscope and Accessories

SAFETY & EFFECTIVENESS DATA SUMMARY

Classification Name: Hysteroscopic Resectoscope and Accessories
Common/Usual Name: Resectoscope and Accessories
Proprietary Name: N/A

Classification: Class II

Hysteroscopic Resectoscope	Reg. # 884.1690	Code # 85 HIH
Endoscopic Electrosurgical Instruments and Accessories	Reg. # 878.4400	Code # 79 JOS

Performance Standards: . Devices are manufactured according to cGMP's, Applicable Harmonized Standards ISO 9001/EN 46001, applicable AAMI/ASTM standards, EN/IEC 60601 Standards.

Material Composition: Surgical grade Stainless Steel (300 Series), Commercially pure titanium , Anodized Aluminum Type 6061, DELRIN or P.E.E.K. Glass (Type BK-7) or Optical Grade Pure Sapphire, Type Z , and PTFE. There are no significant differences to the materials, design or other noted features.

Intended Use: The Henke Sass Wolf Hysterscopic Resectoscopes and Accessories are intended to enable the viewing and resection/coagulation of soft tissue encountered in but not limited to gynecologic, urologic diagnostic and surgical procedures.

Device Description: The HENKE-SASS, WOLF Hysteroscopic Resectoscopes and Accessories are reusable hand-held instruments designed for a means of performing diagnostic and therapeutic procedures. The HENKE-SASS, WOLF Hysteroscopic Resectoscopes and Accessories (available in various lengths and Sizes) have the same operating principals and intended uses as many of the competitive hysteroscopic resectoscopes and accessories already in commercial distribution

Predicate Devices: Henke Sass Wolf GmbH Hysterscopes and Accessories; Smith& Nephew Dyonics Hysterscopes and Accessories, Cooper Surgical RG-27 Series Resectoscope and Accessories , Cooper Surgical HT4 Series Hysterscopes and Accessories, Karl Storz Endoscopic Hysterscopes and Accessories and K954050, Richard Wolf GmbH Hysterscopes and Accessories, Gyrus Axipoler™, Omnitech Systems Inc. Resectoscope Electrodes.

Comparison of Technological Characteristics: The resectoscope and accessories utilize material and design is identical to the predicate devices (Manufactured by HENKE SASS WOLF on an OEM basis). In function, the resectoscope and accessories are the same as the predicate devices.

Safety and Efficacy Information: The HENKE SASS WOLF Resectoscope and Accessories have the same operating principals and intended uses as many of the competitive resectoscopes and accessories already in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 1999

Henke Sass Wolf of America, Inc.
c/o Ellen J. Henke
European Surgical, Inc.
73 Eagles Nest Road
Duxbury, Massachusetts 02332

Re: K991563
Hysteroscopic Resectoscopes and Accessories
Dated: September 2, 1999
Received: September 7, 1999
Regulatory Class: II
21 CFR §884.1690/Procode: 85 HIH

Dear Ms. Henke:

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 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. 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991563

Device Name: Hysteroscopic Resectoscopes and Accessories

Indications For Use:

The HENKE SASS WOLF Hysteroscopic Resectoscopes are intended to provide the physician with a means for endoscopic diagnostic and therapeutic surgical procedures. The HENKE SASS WOLF Resectoscopes and Accessories will include the Sheaths - to establish portals for visualization and surgical access and the electrode devices indicated for resection/coagulation for soft tissue and are intended for the use with the compatible resectoscopes.

The Resectoscopes and Accessories are indicated for use in diagnostic examination and therapeutic surgical procedures of but not limited to: Urological and Gynecological Fields. The surgical applications may include:

Tissue Cutting, removal, and dissection as required or encountered in but not limited to:

* Excision of intrauterine myomas
* Excision of intrauterine polyps
* Lysis of intrauterine adhesions
* Incision of uterine septa

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991563/S001

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

(Optional Format 1-2-96)