AUG 13 1998

K981751

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: Nasopharyngoscope and Accessories

SAFETY & EFFECTIVENESS DATA SUMMARY

Classification Name: Nasopharyngoscope and Accessories
Common/Usual Name: Sinuscope and Accessories
Proprietary Name: N/A

Classification: Class II
Nasopharyngoscope and Accessories # 77 EOB Reg. # 874.4760

Performance Standards: . Devices are manufactured according to cGMP's, Applicable Harmonized Standards ISO 9001/EN 46001, applicable AAMI/ASTM standards, IEC 601-1 Standards.

Material Composition: Shaft; Surgical grade Stainless Steel (300 Series), certified according to ISO 5832/1 and ASTM 899, **Body**; Surgical grade Stainless Steel (300 Series - as above), Commercially pure titanium certified to ASTM B367, Anodized Aluminum Type 6061 with anodized coating per MIL-A-8635F, **Sidearm**; Surgical Grade Stainless Steel (300 Series - as above), **Eyepiece**; DELRIN (Fed. Spec. L-P392A) or P.E.E.K. per MIL-P-46183,Type 1, **Lenses**; Glass (Type BK-7) or Optical Grade Pure Sapphire, Type Z. There are no significant differences to the materials, design or other noted features.

Intended Use: The HENKE- SASS, WOLF Sinuscope is intended to provide the physician with a means of endoscopic diagnostic and therapeutic sinus surgical procedures.

Device Description: The HENKE-SASS, WOLF Sinuscopes are reusable hand-held instruments designed for a means of performing diagnostic and therapeutic sinus procedures. The HENKE-SASS, WOLF Sinuscopes and accessories have the same operating principals and intended uses as many of the competitive sinuscopes and accessories already in commercial distribution

Predicate Devices: Smith& Nephew Richards Sinuscope K932988, Richards Medical Company Endoscopes for Sinus Surgery K874215(manufactured by HENKE SASS WOLF, GmbH)

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

Safety and Efficacy Information: The sinuscope itself is well recognized as being safe and effective for diagnostic and therapeutic sinus procedures. The HENKE SASS WOLF Sinuscopes and accessories have the same operating principals and intended uses as many of the competitive sinuscopes and accessories already in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1998

Ellen J. Henke
Official Correspondent
Henke Sass Wolf of America, Inc.
Soroco Industrial Park, Rte. 131
529 Ashland Avenue
Southbridge, MA 01550

Re: K981751
Sinuscope and Accessories
Dated: May 13, 1998
Received: May 18, 1998
Regulatory class: II
21 CFR 874.4760/Procode: 77 EOB

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 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

510(k) Number (if known): _____

Device Name: Nasopharyngoscope and Accessories (Sinuscope)

Indications For Use:

The HENKE-SASS WOLF of America Inc., Sinuscope is intended to provide the physician with a means for endoscopic diagnostic and therapeutic sinus surgical procedures. The HENKE SASS WOLF of America Inc. Sinuscope Accessories will include Sheaths - to establish portals for visualization and surgical access and the Suction/Irrigation Handle - to remove debris and body fluids from the surgical site and to provide irrigation of the site with a sterile solution such as saline water.

The Sinuscope and accessories are indicated for use in, but not limited to such procedures as examination of sinus passages and cavities, removal of abnormal growths such as polyps and facio-plastic surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981751

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

(Optional Format 1-2-96)