FEB 0 1 2002

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SAFETY & EFFECTIVENESS DATA SUMMARY

Submitters Name, Address & Phone Number:

Henke Sass Wolf of America
Soroco Industrial Park, Rte. 131
529 Ashland Ave.
Southbridge, MA 01550

Submission Correspondent:

Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, NJ 08822
Attention: Lynette Howard

Classification Name: Laparoscope, General & Plastic Surgery
Common / Usual Name: Laparoscope, General & Plastic Surgery
Proprietary Name: Henke Sass Wolf Saphemous Vein Laparoscope

Establishment Registration Number: 1222997

Classification: Class II, Reg. # 876.1500, 78 GCJ General and Plastic Surgery Accessories

Performance Standards: No performance standards have been developed for this device.

Substantial Equivalence:

The HSW Saphenous Vein Laparoscope is substantially equivalent to the Stryker Saphenous Vein Harvest Laparoscope intended use and is compatible for use with the Ethicon's Subcu-Retractor for this purpose. The HSW Saphenous Vein Laparoscope can also be used as a substitute for a standard HSW 5mm Laparoscope in similar intended use applications as outlined in Laparoscope 510(k) K941967.

The intended use of the device to which we claim substantial equivalence:

For severe cases of coronary artery disease, in which blood vessel grafts are used to bypass the site of a blocked artery, a procedure known as coronary artery bypass graft surgery (CABG) is performed. To help reduce patient trauma and cost, an endoscopic technique is used in the saphenous vein harvesting procedure. This minimally invasive approach requires only a single 3-4cm incision made medial to the knee.

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Additional Information – Attachment III – January 28, 2002
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The laparoscope in used in conjunction with Ethicon's Endo-Surgery cannula system to provide a complete visualization system. These laparoscopes were designed to be inserted in the Ethicon sheath to help view the surgical area. To facilitate this, the laparoscope working length was modified. These laparoscopes are reusable and employed in conjunction with other cleared devices, to form a complete system.

Testing conducted to assure safety and effectiveness include but is not limited to:

Electrical Safety:	**EN 60601-1-1, EN 601-2-10**
Electromedical System:	**EN 60601-1-1**

Proposed devices have successfully met the requirements of the above.

Description of the new device:

The Henke Sass Wolf Saphenous Vein Laparoscope is identical in terms of materials and modes of construction, optical performance and safety to the existing line of HSW 5mm Laparoscopes, differing only in working length and angle of view. The materials and basic design are identical.

For the purpose of saphenous vein harvesting, a standard 5mm laparoscope is modified to extend the working length to 300mm.

The HSW Saphenous Vein Laparoscope is substantially equivalent to the Stryker Saphenous Vein Harvest Laparoscope intended use and is compatible for use with the Ethicon's Subcu-Retractor for this purpose. The HSW Saphenous Vein Laparoscope can also be used as a substitute for a standard HSW 5mm Laparoscope in similar intended use applications as outlined in Laparoscope 510(k) K941967.

Intended Use:

For use in Endoscopic Saphenous Vein harvesting procedures.

Caution: Federal (USA) law restricts this device to sale, distribution, and use by, or on the order of, a physician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 01 2002

Henke Sass Wolf of America, Inc.
c/o Ms. Lynette Howard
Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, New Jersey 08822

Re: K013611
Trade/Device Name: Henke Sass Wolf Saphenous Vein Laparoscope
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 31, 2001
Received: November 5, 2001

Dear Ms. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

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

Enclosure

Henke Sass Wolf of America

STATEMENT OF INDICATION FOR USE

510(k) Number: K013611

Device Name: Henke Sass Wolf Saphenous Vein Laparoscope

Indications for Use:

Intended for use in Endoscopic Saphenous Vein harvesting procedures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013611