

MAR 18 2008

510(K) Submission

K080560

- 1. Applicant's Name & Address:** Henke Sass Wolf of America
44 Southbridge Rd.
Dudley, MA 01571

John Kingston
(508) 671-9300
- 2. Contact Person and Telephone Number:** Lynette Howard
(908) 788-4580
- 3. Representative / Consultant:** Lynette Howard
106 East 5th Avenue
Mount Dora, FL 32757
Phone: (908) 788-4580
Fax: (352) 383.8338
e-mail: Lylehoward@aol.com
- 4. Device Trade or Proprietary Name:** Henke Sass Wolf
Arthroscope
- 5. Device Common Name / Classification Name:** Arthroscope
- 6. Establishment Registration Number:** 1222997
- 7. Address of Manufacturing Site:** Henke-Sass, Wolf GmbH
Postfach 2459
78507 Tuttlingen
Germany

Registration #: 8010418
- 8. Classification of Device under Section 513:** Class II, HRZ
Regulation #: 888.1100

9. Labels and Instructions for Use:

See Section 8 & 9

10. Drawings of device:

See Section 10

11. Marketed Device(s) to which the claim of substantial equivalence is claimed:

The Henke Sass Wolf of America Laparoscopes are substantially equivalent to the Henke Sass Wolf of America Laparoscope - K962075 and the Smith & Nephew, Inc. Arthroscope – K971253 in design, materials, methods of construction and intended use.

See Section 11

12. The intended use of the devices to which we claim substantial equivalence:

The Henke Sass Wolf of America Arthroscopes (K962075) are intended to be used by surgeons in diagnostic and therapeutic procedures. Arthroscopic minimal invasive procedures are performed in the knee, shoulder, wrist (carpal tunnel syndrome), temporal-mandibular joint, ankle, elbow and feet (plantar fascia release). The benefits realized through the use of arthroscopic procedures include: the minimal trauma experienced from the small punctures necessary to gain access for the Arthroscope and compared to a complete open procedure, the ability to gain visual access to areas of the anatomy which would be extremely difficult and require substantially more complicated procedures to approach by other methods.

Diagnostic procedures are used when it is difficult to make an exact diagnosis without direct visual observation. Therapeutic procedure provide a means for repair of cartilage, detachment of lesions and removal of debris. Procedural names include subacromial decompression, notchplasty, meniscectomy, synovectomy, small joint arthroscopy, examination of the menisco-synovial junction, access and release of carpal tunnel ligament and plantar fascia release.

The Smith & Nephew, Inc. Rigid Arthroscope & Accessories – K971253, are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the shoulder, knee, elbow, ankle, wrist and jaw, also to provide illumination and visualization during arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

The Smith & Nephew, Inc. Endoscopy Division Sterile Disposable Endoscopic Surgery Blades – K971253 are indicated for use during arthroscopic resection of soft and osseous tissue in various large and small articular cavities including the hip joint. Blades which are size-appropriate are indicated for use in the following joints: shoulder, knee, elbow, ankle, wrist, jaw and the hip joint.

13. Description of the new device:

The Henke Sass Wolf of America’s Arthroscope is identical in terms of materials and modes of construction, optical performance and safety to Henke Sass Wolf of America’s current Arthroscope and the Smith & Nephew Arthroscope. The only difference from the current Henke Sass Wolf of America’s Arthroscope is the new intended use for hip surgery. This indication for use is already in place for the Smith & Nephew Arthroscope.

The arthroscope is a long tube containing a series of lenses. At the distal end, an objective lens captures the image of the object. A series of rod lenses relay the image along the length of the tube. At the proximal end, in the case of a direct view model, an ocular lens forms an image for viewing directly with the human eye. In the case of a videarthroscope, a proximal coupling lens relays the image to a CCD (charged couple device used as an electronic video sensor chip).

Arthroscopes generally come in two diameters, 2.7mm and 4.0mm, although other sizes are sometimes offered. Larger size arthroscopes are used for general viewing. This is due to the preferable larger and brighter image achievable with larger diameter optical components. The small sizes are used where access to the surgical site is restricted.

Arthroscopes generally come in several “directions of view”, 0°, 30°, 70°, 90° and 110°, though others are sometimes offered. The center axis of the field of view of the 0° scope is along the normal axis of the Arthroscope. The other “direction of view” instruments are referenced from the scope normal axis. The various “directions of view” permit or facilitate viewing of different parts of the relevant anatomy.

All arthroscopes also contain glass fibers for illumination of the surgical site.

Henke Sass Wolf Arthroscopes are provided in Autoclavable and Non-Autoclavable models.

The characteristics which distinguish the two models are:

Characteristics	Non-Autoclavable	Autoclavable
Material of external optical elements	Conventional optical quality glass	Sapphire
Mounting Methods for external optical elements	Epoxied or mechanically restrained	Soldered
Bonding methods mechanical components	Epoxied	Welded

The imaging systems incorporated consist of:

- An objective lens which performs the image acquisition.
- A series of rod lenses relay the image from the distal end to the proximal end of the Arthroscope.
- A final optical element at the proximal end of the Arthroscope. In the case of a direct view model, an ocular lens forms an image for viewing directly with the human eye. In the case of a videoarthroscope, a proximal coupling lens relays the image to a CCD (charged couple device used as an electronic video sensor chip).

Illumination of the surgical site is provided by fiber optics internal to the Arthroscope. A mechanical coupling located at the proximal end of the device provides a method of connecting flexible light guides to external light sources.

Specifications for the proposed device:

Arthroscope Diameter (mm)	Direction of View (degrees)	Field of View (degrees)	*Eyepiece Magnification	Working Length (mm)
2.3-2.9	0, 30, 70	~ 85	24	~ 195
4.0	0, 30, 45, 70, 110	~ 105	21	~ 185
Short Arthroscope Diameter (mm)	Direction of View (degrees)	Field of View (degrees)	*Eyepiece Magnification	Working Length (mm)
1.7-1.9	0, 30	~ 85	21	~ 60
2.3-2.9	0, 30, 70	~ 85	24	~ 70/140

*Eyepiece magnification pertains to direct view arthroscopes only.

Notes:

- Locking Device can be either Storz Type, Stryker Speedlock, J-lock or Linvatec Quick Latch locking mechanism
- Adapters for connection to all conventional light-guides are supplied as standard.

Life supporting or Life Sustaining? No

Implanted (Short term or Long term)? No

Device incorporates software? No

Summary of:

Device Design

The Henke Sass Wolf Arthroscope is identical in terms of materials and modes of construction, optical performance and safety to the existing line of HSW Arthroscopes, differing only in an additional intended use.

Note: The Smith & Nephew Arthroscopes are manufactured by Henke Sass Wolf, GmbH facility.

Henke Sass Wolf manufactures autoclavable and non-autoclavable models. The autoclavable models are identified by the word "Autoclavable" on the instrument. Both models, autoclavable and non-autoclavable, are sold as non-sterile, reusable instruments.

Materials

Component	Material #	German Standard	USA UNS	ASTM
Shaft	Stainless Steel		QQ-S-763 QQ-W-423 QQ-S-764	
Body	Stainless Steel		QQ-S-763 QQ-W-423 QQ-S-764	
	Titanium			B367
Sidearm	Stainless Steel		QQ-S-763 QQ-W-423 QQ-S-764	
	Titanium			B367
Eyepiece	P.E.E.K.		MIL-P-46183 – type 1	
Lenses	Glass	BK-7 (Schott Glass No. 517642)		
	Sapphire	Optical Grade Pure Sapphire, Type 2		

Additional Materials:

Solder: The solder used to seal the objective lens in the autoclavable modes of the Arthroscope is the lead free alloy "CASTIN".

Adhesive: The adhesive used to seal the objective lens in the non-autoclavable

models of the Arthroscope is Loctite product # 3321.

The external exposure of either of the above materials is limited to an area of 0.95 millimeters². This is equivalent to a circle with a diameter of 1.1 millimeters.

The materials of construction are identical to the Henke Sass Wolf of America Arthroscope – K962075 and the Smith & Nephew, Inc., Arthroscope – K971253. All materials used are medical grade. These devices are not implantable device.

Physical properties

The physical properties are identical to the Henke Sass Wolf of America Arthroscope – K962075 and the Smith & Nephew, Arthroscope – K971253.

Is the Device Sterile? No

The device is intended to be sterilized prior to use. The Arthroscopes Endoscopes are designed to facilitate cleaning and disinfection, and are validated for clean ability and repeat sterilization.

Instructions for cleaning and sterilization are included in the instructions for use. Sterilization and disinfection validation includes Sterrad 100S and is performed to assure an SAL of 10⁻⁶ per AAMI / ISO Standards for non-autoclavable scopes.

Steam Sterilization as per ANSI/AAMI standards is used for the autoclavable scopes.

All sterilization methods are defined in the instructions for use.

Is the Device for single use? No

Is the Device for home use or prescription use? Yes, Prescription Use

Does the Device contain drug or biological product as a component? No

Is the Device a kit? No

Is this a software-controlled device? No

14. The intended use of the new device:

The HSW Arthroscope and accessories is a tubular endoscopic device with accessory devices which attach to the Arthroscope and is intended to examine and / or perform surgery on the interior of a joint. Arthroscopic minimal invasive procedures are performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporal-mandibular joint, ankle, elbow and feet (plantar fascia release).

Diagnostic procedures are used when it is difficult to make an exact diagnosis without direct visual observation. Therapeutic procedures provide a means for repair of cartilage, detachment of lesions and removal of debris. Procedural names include subacromial decompression, notchplasty, meniscectomy, synovectomy, small & large joint arthroscopy, examination of the menisco-synovial junction, access and release of carpal tunnel ligament and plantar fascia release.

15. Comparison of the new device to the marketed device(s):

Refer to Section 11

16. Summary of Risk Analysis:

See Section 14

17. Summary of safety and effectiveness of the new device:

See Section 15

18. Testing conducted to assure safety and effectiveness includes but is not limited to:

Biological Evaluation of Medical Devices – ISO 10993-1, ISO 10993-5, ISO 10993-12

Electrical Safety Requirements as per IEC 601-2-18 as a type BF or Type CF applied as part of medical electrical equipment.

AAMI / ISO Standards for Sterilization of Medical Devices

For Sterile Device: Devices are intended to be sterilized prior to use as described below:

1. Name, Address, telephone number, contact person of contract sterilizer:

N/A

2. Sterilization Method:

Steris, Sterrad or Autoclaving

Non-Autoclavable Scopes

Sterilize by one of the following methods:

Steris System 1 Processor

Sterilize the device using the Steris System 1 sterilization process. Follow all recommended directions and warnings from STERIS Corporation in the use of the Steris System 1 Processor.

Sterrad 100s Sterilization System

Sterilize the device using the Sterrad 100s Sterilization System according to ANSI/AAMI/ISO 14937 (2000) Sterilization of Medical Devices.. Please follow your Sterrad 100s System Operator's Manual instructions for use when processing these devices.

Autoclavable Scopes

Autoclave Wrapped

Follow standard hospital procedure for:

Pre-Vacuum methods at 270° F - 275° F (132° C - 135° C) for 4 minutes; or

Gravity methods at 270° F - 275° F (132° C - 135° C) for 10 minutes.

In addition to autoclave wrapped methods, you may also use one of the following sterilization methods:

Steris System 1 Processor – Refer to the sterilization parameters under “Non-Autoclavable Scopes”.

Prior to all methods of sterilization or disinfection the scope must be cleaned thoroughly. The scopes should be sterilized or disinfected in a container, which secures the instrument in place.

3. Description of method that is used to validate the sterilization cycle:

Sterilization validation was conducted for predicate devices. There are no significant differences between the proposed device and HSW predicate devices that would compromise the sterilization process and/or results. The instructions for sterilization are identical as those for the Smith & Nephew predicate devices.

In addition, Sterilization Validation was completed for the Henke-Sass Wolf GmbH 0° 10mm Operative Laparoscope (Part Number 83 000 4877) for the Sterrad 100S Sterilization System. This scope was chosen as a “worst case” scenario and is applicable to the proposed device.

See Section 16

4. The sterility assurance level (SAL):

Validation conducted to SAL of 10⁻⁶

5. Description of packaging to maintain the devices sterility:

N/A

6. The radiation dose, for radiation sterilized devices:

N/A



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Henke Sass Wolf of America
% Ms. Lynette Howard
Submission Correspondent
106 East 5th Avenue
Mount Dora, Florida 32757

MAR 18 2008

Re: K080560

Trade/Device Name: Henke Sass Wolf Arthroscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRZ
Dated: February 26, 2008
Received: February 29, 2008

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.

Page 2 – Ms. Lynette Howard

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080560

Device Name:

Indications for Use:

The HSW Arthroscope and accessories is a tubular endoscopic device with accessory devices which attach to the Arthroscope and is intended to examine and / or perform surgery on the interior of a joint. Arthroscopic minimal invasive procedures are performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporal-mandibular joint, ankle, elbow and feet (plantar fascia release).

Prescription Use x
(Part 21 CFR 801 Subpart D)

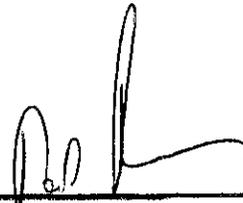
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K0805660