June 8, 2018

Henke-Sass, Wolf GmbH
Anna Reifschneider
Regulatory Affairs Manager
Keltenstrasse 1
Tuttlingen, 78532
Germany

Re: K173070
Trade/Device Name: HSW Resection Instruments
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, FAS, FAJ
Dated: May 7, 2018
Received: May 11, 2018

Dear Anna Reifschneider:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173070

Device Name
HSW Resection Instruments

Indications for Use *(Describe)*
The Henke-Sass, Wolf Resection Instruments are intended to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples of use of the product include the visualization and manipulation of anatomy, ablation, incision, coagulation, cauterization of minor bleedings, resection of tissue, vaporization and enucleation, and as the surgeon deems appropriate. The instruments are intended for use in general urological and gynecological surgery through the minimally invasive approach, by utilizing natural orifices to access the surgical site. The system's use is intended for, but not limited to the following types of procedures:

. Dilation of the urethra, and cold-slitting of urethral strictures
. Trans-urethral incision and resection of the prostate
. Trans-urethral removal of bladder tumor
. Trans-cervical resection and ablation of the endometrium
. Trans-cervical resection of fibroids

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Number: K173070

1. Applicant Information

Date Prepared:	June 5, 2018
Company Name and Address:	Henke-Sass, Wolf GmbH Keltenstrasse 1 78532 Tuttlingen Germany Ph: +49 (7462) 946-6147
Contact Person:	Ms. Anna Reifschneider, RAC Regulatory Affairs Manager

2. Device Information

Common Name:	Resectoscopic Accessories
Regulation Name:	Hysteroscope and accessories
Regulation Number:	21 CFR 884.1690
Product Code:	HIH (Hysteroscope (And Accessories)), FAJ (Cystoscope and Accessories, Flexible/Rigid), FAS (Electrode, Electrosurgical, Active, Urological)
Device Class:	II
Device Name:	HSW Resection Instruments

3. Predicate Devices

The legally marketed devices to which substantial equivalence is being claimed are:

510(k) Number:	K040390
Applicant:	Stryker Endoscopy
Device Name:	Stryker Urology and Gynecology Hardware System
Regulation Number:	21 CFR 884.1690
Product Code:	HIH, FAJ, FAS, and KQT
Device Class:	II

The predicate device has not been subject to a design related recall.

4. Device Description

The Henke-Sass, Wolf Resection Instruments consist of various components that assemble into and/or work as a diagnostic and therapeutic resectoscopic system in urology and gynecology.

This submission is comprised of rigid working elements (resectoscopes), sheaths, obturators, electrodes (bipolar and monopolar), and HF cables. With the exception of the electrodes, the subject devices are provided non-sterile and reusable. The electrodes are provided sterile and are single-use.

Examples of use of the product include the visualization and manipulation of anatomy, biopsy, and as the surgeon deems appropriate.

The following table provides a descriptive list of each of the subject device components:
Working Elements

Description (model)	Model Number
Resectoscope working element active, for 2.9mm scope, handle open, monopolar	8300032281
Resectoscope working element active, for 2.9mm scope, handle closed, monopolar	8300032501
Resectoscope working element active, for 4.0mm scope, monopolar	8300032481
Resectoscope working element active, for 4.0mm scope, monopolar	8300032483
Resectoscope working element active, for 4.0mm scope, handle closed, monopolar	8300032485
Resectoscope working element active, for 4.0mm scope, handle open, monopolar	8300032486
Resectoscope working element passive, for 2.9mm scope, handle open, monopolar	8300032280
Resectoscope working element passive, for 2.9mm scope, handle closed, monopolar	8300032500
Resectoscope working element, passive, monopolar for 2.9mm scope	8300032419
Resectoscope working element passive, for 4.0mm scope, monopolar	8300032480
Resectoscope working element passive, for 4.0mm scope, monopolar	8300032482
Resectoscope working element passive, for 4.0mm scope, handle closed, monopolar	8300032484
Resectoscope working element passive, for 4.0mm scope, handle open, monopolar	8300032256
Resectoscope working element passive, for 2.0mm scope, monopolar	8300032503
Resectoscope working element passive, for 2.7mm scope, monopolar	8300032506
Resectoscope working element passive, for 2.9mm scope, bipolar (saline)	8300032327
Resectoscope working element passive, for 4mm scope, bipolar (saline)	8300032344
Resectoscope working element active, for 4mm scope, bipolar (saline)	8300032345
Laser resectoscope working element passive, for 2.9mm scope, with guiding channel for laser probe up to 0.8mm	8300032254
Laser resectoscope working element passive, for 2.9mm scope, with guiding channel for laser probe up to 1.2mm	8300032255
Laser resectoscope working element passive, for 4mm scope, with guiding channel for laser probe up to 0.8mm	8300032240
Laser resectoscope working element passive, for 4mm scope, with guiding channel for laser probe up to 1.2mm	8300032241
Laser resectoscope working element passive, for 4mm scope, with interchangeable guiding channel for laser probe	8300035301
Laser resectoscope adapter for laser probe, rotatable	8300032243
Laser resectoscope adapter for laser probe, rotatable, long	8300032244
TB laser resectoscope adapter for laser probe	8300039283
Laser resectoscope guiding channel for laser probe up to 0.8mm	8300032246
Laser resectoscope guiding channel for laser probe up to 1.0mm	8300032247
Laser resectoscope guiding channel for laser probe up to 1.2mm	8300032248

Laser resectoscope guiding channel for laser probe up to 1.4mm	8300032249
Laser resectoscope guiding channel for laser probe up to 0.8mm with retractor	8300032250
Laser resectoscope guiding channel for laser probe up to 1.0mm with retractor	8300032251
Laser resectoscope guiding channel for laser probe up to 1.2mm with retractor	8300032252
Laser resectoscope guiding channel for laser probe up to 1.4mm with retractor	8300032253

Sheaths

Description (model)	Model Number
Resectoscope standard sheath 11Fr.	8300032502
Resectoscope standard sheath 13 Fr.	8300032504
Resectoscope standard sheath 17.5 Fr.	8300032323
Resectoscope standard sheath 19Fr.	8300032282
Resectoscope standard sheath 24Fr.	8300032260
Resectoscope standard sheath 27Fr.	8300032261
Resectoscope standard sheath 24Fr. with central valve	8300032489
Resectoscope standard sheath 27Fr. with central valve	8300032490
Resectoscope inner sheath 17.5 Fr. quick lock	8300032325
Resectoscope inner sheath 19Fr. with oblique distal tip, fixed stopcock	8300032283
Resectoscope inner sheath 19Fr. with oblique distal tip, rotatable stopcocks	8300032286
Resectoscope inner sheath 24Fr., fixed stopcock	8300032262
Resectoscope inner sheath 27Fr., fixed stopcock	8300032265
Resectoscope inner sheath 24Fr., rotatable stopcocks	8300032270
Resectoscope inner sheath 27Fr., rotatable stopcocks	8300032272
Resectoscope inner sheath 24 Fr., quick lock, rotatable stopcocks	8300032335
Resectoscope outer sheath 22Fr., fixed stopcock, all aroundperforation	8300032284
Resectoscope outer sheath 26Fr. fixed stopcock, all aroundperforation	8300032263
Resectoscope outer sheath 26Fr. fixed stopcock, top and bottom perforation	8300032495
Resectoscope outer sheath 26Fr. fixed stopcock, all around slot hole perforation	8300032586
Resectoscope outer sheath 28.5Fr., fixed stopcock, all aroundperforation	8300032266
Resectoscope outer sheath 18.5Fr. with rotatable stopcocks	8300032324
Resectoscope outer sheath 22Fr., all around perforation, rotatable stopcocks	8300032287
Resectoscope outer sheath 26Fr., all around perforation, rotatable stopcocks	8300032271
Resectoscope outer sheath 26Fr., top and bottom perforation, rotatable stopcocks	8300032496
Resectoscope outer sheath 26Fr., top perforation, rotatable stopcocks	8300032497
Resectoscope outer sheath 26Fr., all around slot hole perforation, rotatable stopcocks	8300032587
Resectoscope outer sheath 26Fr., top slot hole perforation, rotatable stopcocks	8300032588
Resectoscope outer sheath 26Fr. quick lock, all around perforation, rotatable stopcocks	8300032333
Resectoscope outer sheath 28.5Fr. all around perforation, rotatable stopcocks	8300032273

Electrodes

Description (model)	Model Number
Loop electrode 11Fr., angled, monopolar, for 2.0mm scope	8300039108
Loop electrode 11Fr., angled, monopolar, for 2.0mm 0°C scope, small	8300039110
Ball electrode 11Fr., monopolar, for 2.0mm scope	8300041000
Knife electrode 11Fr., monopolar, for 2.0mm scope	8300039114
Hook-like electrode 11Fr., monopolar, for 2.0mm scope	8300039116

Loop electrode 13Fr., angled, monopolar, for 2.7mm scope	8300039109
Loop electrode 13Fr., angled, monopolar, for 2.7mm scope, small	8300039111
Ball electrode 13Fr., monopolar, for 2.7mm scope	8300039112
Knife electrode 13Fr., monopolar, for 2.7mm scope	8300039115
Hook-like electrode 13Fr., monopolar, for 2.7mm scope	8300039117
Loop electrode 19Fr. monopolar, for 2.9mm 12° scope	8300039074
Loop electrode 19Fr. monopolar, straight, for 2.9mm scope	8300039075
Knife electrode 19Fr. monopolar, for 2.9mm scope	8300039076
Ball electrode 19Fr. monopolar, for 2.9mm scope	8300039077
Roller electrode 19Fr. monopolar, for 2.9mm scope	8300039078
HF roller electrode, 19Fr., monopolar scope, for 2.9mm scope	8300039079
Loop electrode 24Fr. angled 30°, monopolar, for 4mm scope	8300039081
Loop Electrode 24Fr. angled 30°, monopolar, cutting wire 0,40 mm	8300039256
Loop electrode 24Fr. straight, monopolar, for 4mm scope	8300039083
Knife electrode 24Fr. monopolar, for 4mm scope	8300039088
Ball electrode 3mm 24Fr. monopolar, for 4mm scope	8300039090
Ball electrode 5mm 24Fr. monopolar, for 4mm scope	8300039092
Roller electrode 3mm 24Fr. monopolar, for 4mm scope	8300039094
Roller electrode 5mm 24Fr. monopolar, for 4mm scope	8300039096
Conical electrode 24Fr. monopolar, for 4mm scope	8300039098
Loop electrode 24Fr. 90°, monopolar, for 4mm 0° scope	8300039264
Spiked Vaporisation electrode 3mm, monopolar, for 4mm scope	8300039099
Spiked Vaporisation electrode 5mm, monopolar, for 4mm scope	8300039100
Vaporisation electrode 3mm, monopolar, for 4mm scope	8300039101
Vaporisation electrode 5mm, monopolar, for 4mm scope	8300039102
Band vaporisation electrode monopolar, for 4mm scope	8300039106
Band electrode monopolar, for 4mm 0°scope	8300039104
Band electrode monopolar, for 4mm 30°scope	8300039476
Loop electrode 27Fr. angled 30°, monopolar, for 4mm scope	8300039082
Loop electrode 27Fr. straight, monopolar, for 4mm scope	8300039084
Knife electrode 27Fr. monopolar, for 4mm scope	8300039089
Ball electrode 3mm 27Fr. monopolar, for 4mm scope	8300039091
Ball electrode 5mm 27Fr. monopolar, for 4mm scope	8300039093
Roller electrode 3mm 27Fr. monopolar, for 4mm scope	8300039095
Roller electrode 5mm 27Fr. monopolar, for 4mm scope	8300039097
Loop electrode 27Fr. 90°, monopolar, for 4mm 0° scope	8300039086
Knife electrode 27Fr., monopolar, for 4mm scope	8300039089
Spiked Vaporisation electrode 3mm, 27Fr. monopolar, for 4mm scope	8300039268
Spiked Vaporisation electrode 5mm, 27Fr. monopolar, for 4mm scope	8300039270

Vaporisation electrode 3mm, 27Fr. monopolar, for 4mm scope	8300039272
Vaporisation electrode 5mm, 27Fr. monopolar, for 4mm scope	8300039273
Loop electrode 17Fr., 30°, bipolar (saline), for 2.9mm	8300039118
Loop electrode 17Fr., bipolar (saline), for 2.9mm scope	8300039122
Knife electrode 17Fr., bipolar (saline), for 2.9mm scope	8300039119
Ball electrode 2mm 17Fr., bipolar (saline), for 2.9mm scope	8300039120
Roller electrode 2mm 17Fr., bipolar (saline), for 2.9mm scope	8300039121
Loop electrode 24Fr., bipolar (saline), for 4mm scope	8300039127
Knife electrode 24Fr., bipolar (saline), for 4mm scope	8300039124
Coagulation ball electrode 24Fr., bipolar (saline), for 4mm scope	8300039125
Coagulation roller electrode 24Fr., bipolar (saline), for 4mm scope	8300039126
Loop electrode 90° 24Fr., bipolar (saline), for 4mm scope	8300039128

Obturators

Description (model)	**Model number**
Obturator for 13 Fr. Resectoscope sheath	8300032505
Obturator for 11 Fr. Resectoscope sheath	8300032422
Obturator for 17.5 Fr. Resectoscope sheath	8300032326
Obturator for 19 Fr. Resectoscope sheath	8300032285
Obturator for 24 Fr. Resectoscope sheath	8300032264
Obturator for 24Fr. Resectoscope sheath, quick lock	8300032343
Obturator for 27 Fr. Resectoscope sheath	8300032267
Visual obturator for 19 Fr. Resectoscope sheath	8300032288
Visual obturator for 24 Fr. Resectoscope sheath	8300032279
Visual obturator for 27 Fr. Resectoscope sheath	8300032276
Visual obturator with 6Fr. working channel for 24 Fr. Resectoscopesheath	8300032277
Visual obturator with 9Fr. working channel for 27 Fr. Resectoscopesheath	8300032278
Timberlake obturator for 24 Fr. Resectoscope sheath	8300032274
Timberlake obturator for 27 Fr. Resectoscope sheath	8300032275

HF Cables

Description (model)	**Model number**
HF connection cable Martin, 3 m length	8300040170
HF connection cable Storz/Erbe, 3 m length	8300040172
HF connection cable Valleylab-Bovie, 3m length	8300040171
HF connection cable, Valleylap, 4.5m length	8300032353

5. Indications for Use

The Henke-Sass, Wolf Resection Instruments are intended to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples of use of the product include the visualization and manipulation of anatomy, ablation, incision, coagulation,

cauterization of minor bleedings, resection of tissue, vaporization and enucleation, and as the surgeon deems appropriate. The instruments are intended for use in general urological and gynecological surgery through the minimally invasive approach, by utilizing natural orifices to access the surgical site. The system's use is intended for, but not limited to the following types of procedures:

. Dilation of the urethra, and cold-slitting of urethral strictures
. Trans-urethral incision and resection of the prostate
. Trans-urethral removal of bladder tumor
. Trans-cervical resection and ablation of the endometrium
. Trans-cervical resection of fibroids

The subject and predicate devices have the same intended use and the same indications for use.

6. Comparison of Technological Characteristics

Device & Predicate Device(s):	Subject Device (K173070)	Predicate (K040390)
General Device Characteristics		
Manufacturer	Henke-Sass, Wolf GmbH	Same
Features	Resectoscope sheath, handle, receptacles for HF cables, and guiding tubes for electrodes/laser fibers	Same
Working Elements		
Materials	Stainless steel, PTFE	Same
Diameter	2.0 – 4.0 mm scopes	Same
Types	Active, passive	Same
HF ports (#)	2	Same
Electrosurgical mode	Monopolar and Bipolar	Same
Electrodes		
Shapes	Loops, Knives (needles), Balls, and Rollers	Same
Sterile	Provided sterile (EtO)	Provided non-sterile
Materials	Stainless steel, PTFE	Same
Insulation Material	PTFE	Same
Diameter	11 Fr. – 27 Fr.	19 Fr. – 27 Fr.
Electrosurgical mode	Monopolar and Bipolar	Same
Sheaths		
Materials	Stainless steel, Ceramic (ZrO2)	Same
Diameter	19 Fr. – 27 Fr. (inner) 22 Fr. – 28.5 Fr. (outer) 11 Fr. – 27 Fr. (standard)	22 Fr. – 27 Fr. (inner) 24 Fr. – 28 Fr. (outer) 24 Fr. – 27 Fr. (standard)
Outer sheath tip design	Round drilled flushing holes	Same

Stop Cocks	2, above and below (outer) 1, below (standard)	Same
Obturators		
Materials	Stainless steel	Same
Diameter	11 Fr. – 27 Fr.	22 Fr. – 27 Fr.
Tip design	Rounded tip	Same

The HSW Resection Instruments have differences in technological characteristics (see above table) when compared to the predicate device. These technological differences do not raise different questions of safety or effectiveness.

7. Non-Clinical Performance Data

The risk analysis was carried out in accordance with ISO 14971.

Bench Testing

Bench testing was conducted to verify the performance of the Henke-Sass, Wolf Resection Instruments. Design verification testing was conducted to evaluate the functional and electrical performance of the subject devices, which included:

- Visual inspection
- Resection Setup Mechanical Functionality
- Leakage Test and Flow Measurement
- Functional Test (Monopolar and Bipolar electrodes)

Sterility and Shelf Life

For the sterile electrodes, EtO sterilization validation per ISO 11135:2014and package integrity testing per ISO 11607-1:2014 – 11 were conducted. In addition, transport validation and accelerated aging testing were performed for the sterile electrodes in order to confirm the five-year shelf life.

In addition, the reusable Henke-Sass, Wolf Resection Instruments were validated for manual and automated cleaning with subsequent steam sterilization to provide a sterility assurance level of 10-6. The reprocessing validation was conducted in accordance with the 2015 FDA guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

The subject devices demonstrate conformance with the following recognized standards:

Electrical Safety and performance requirements:

- IEC 60601-1:2005 + A1:2012, C1:2009 + A2:2010 Medical Electrical Equipment - Part 1.1 General requirements for safety and essential performance.
- IEC 60601-2-2 Edition 5.0 2009-02 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories [Including: Technical Corrigendum 1 (2014)]
- IEC 60601-1-6:2010 (Third Edition) + A1:2013 Medical electrical equipment - Part 1-6: Particular requirements for the basic safety and essential performance: Usability
- IEC 60601-2-18 Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

Biocompatibility:

- Cytotoxicity - ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Sensitization - ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Irritation - ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

The results of the non-clinical performance testing demonstrated that the subject devices meet pre-defined design and performance acceptance criteria. Results of all non-clinical testing support the safety and effectiveness of the subject device.

8. Conclusion

The performance data support the safety and effectiveness of the subject device and demonstrate that the subject device is substantially equivalent to the predicate device.