December 7, 2017

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

Re: K171336
Trade/Device Name: Cystoscope 4.0mm autoclavable 0° WL 302mm; Hysteroscope 4.0mm autoclavable 0° WL 302mm; Cysto-Urethroscope Sheath 19 Fr.; Bridge for 17-25 Fr. Cysto-Urethroscope Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ, HIH
Dated: October 27, 2017
Received: October 27, 2017

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171336

Device Name
Cystoscope 4.0mm autoclavable 0° WL 302mm; Hysteroscope 4.0mm autoclavable 0° WL 302mm; Cysto-Urethroscope Sheath 19 Fr.; Bridge for 17-25 Fr. Cysto-Urethroscope Sheath

Indications for Use *(Describe)*

Indications for Use

a. Endoscopes

The Henke-Sass, Wolf Cystoscopes/Hysteroscopes are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of the anatomy, as the surgeon deems appropriate. The Henke-Sass, Wolf Cystoscopes/Hysteroscopes are intended to be used in general urological and gynecological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site.

b. Urology Instruments

The Henke-Sass, Wolf Urology Instruments in combination with endoscopes are intended to provide the user with the means for endoscopic visualization during examination, diagnosis and therapy of the lower urinary tract in conjunction with endoscopic accessories, or as the surgeon deems appropriate. The instruments are intended for use in urological procedures through the minimally invasive approach, by utilizing natural orifices to access the surgical site.

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: **171336**

5.1 Sponsor Information

Date Prepared:	December 7th, 2017
Company Name and Address:	Henke-Sass, Wolf GmbH Keltenstrasse 1 78532 Tuttlingen Germany
Contact Person:	Anna Reifschneider, RAC Regulatory Affairs Manager

5.2 Device Information

Device Type:	Cystoscopes, Hysteroscopes and Accessories
Regulation Description:	Endoscope and Accessories
Review Panel:	Gastroenterology/Urology, Obstetrics/Gynecology
Regulation Number:	21 CFR 876.1500
Product Code:	FAJ, HIH
Device Class:	II
Device Name:	Cystoscope 4.0mm autoclavable 0° WL 302mm; Hysteroscope 4.0mm autoclavable 0° WL 302mm; Cysto-Urethroscope Sheath 19 Fr.; Bridge for 17-25 Fr. Cysto-Urethroscope Sheath

5.3 Predicate Device

The legally marketed device to which substantial equivalence is being claimed is:

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

5.4 Device Description

The Henke-Sass, Wolf Cystoscopes, Hysteroscopes and Accessories are composed of cystoscopes, hysteroscopes and cystoscopic accessories, which provide the user with the means for endoscopic diagnostic and therapeutic procedures. Examples of use of the product include the visualization and manipulation of anatomy, biopsy, and as the surgeon deems appropriate.

5.5 Indications for Use

a. Endoscopes:

The Henke-Sass, Wolf Cystoscopes/Hysteroscopes are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of the anatomy, as the surgeon deems appropriate. The Henke-Sass, Wolf Cystoscopes/Hysteroscopes are intended to be used in general urological and gynecological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site.

b. Urology Instruments:

The Henke-Sass, Wolf Urology Instruments in combination with endoscopes are intended to provide the user with the means for endoscopic visualization during examination, diagnosis and therapy of the lower urinary tract in conjunction with endoscopic accessories, or as the surgeon deems appropriate. The instruments are intended for use in urological procedures through the minimally invasive approach, by utilizing natural orifices to access the surgical site.

5.6 Summary of Substantial Equivalence

The Henke-Sass, Wolf Cystoscopes, Hysteroscopes and Accessories are substantially equivalent to the existing 510(k) cleared devices under the predicate Stryker Urology and Gynecology Hardware System (K040390). The indications for use of the Henke-Sass, Wolf Cystoscopes, Hysteroscopes and Accessories are substantially equivalent to the predicate device. The Henke-Sass, Wolf Cystoscopes, Hysteroscopes and Accessories do not incorporate any special technology or characteristics when compared to its predicate device.

5.7 Non-Clinical Performance Data

Bench testing was conducted to verify the performance of the Henke-Sass, Wolf Cystoscopes, Hysteroscopes, and Accessories. Design verification testing was conducted to evaluate the mechanical, optical, and illumination performance.

The cleaning instructions were also validated. The Henke-Sass, Wolf Cystoscopes, Hysteroscopes, and Accessories has been validated for manual and automated cleaning as well as steam sterilization to provide a sterility assurance of 10^{-6}. The devices are provided non-sterile. The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971.

The subject devices demonstrate conformance with the following recognized standards and guidances:

- 510(k) submission guidance for Hysteroscopes and Gynecology Laparoscopes;
- IEC 60601-2-18, Sec. 201.11.1.2.2
- ISO 8600-1;
- ISO 8600-3;
- ISO 8600-4;
- ISO 8600-5;
- ISO 8600-6.

Results show that the subject device has met pre-defined design and performance acceptance criteria. Results of all non-clinical testing support the safety and effectiveness of the subject devices.

5.8 Technological Characteristics

The subject device compares to the legally marketed device as follows:

Device	**Subject Device:** **Henke-Sass, Wolf Cystoscopes, Hysteroscopes, and Accessories**	**Predicate Device:** **K040390 - Stryker Urology and Gynecology Hardware System**
Applicant	Henke-Sass, Wolf	Stryker Endoscopy
510(k) number	Not yet assigned	K040390
Indications for Use	**a. Endoscopes:** The Henke-Sass, Wolf Cystoscopes/Hysteroscopes are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of the anatomy, as the surgeon deems appropriate. The Henke-Sass, Wolf Cystoscopes/Hysteroscopes are intended to be used in general urological and gynecological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site. **b. Urology Instruments:** The Henke-Sass, Wolf Urology Instruments in combination with endoscopes are intended to provide the user with the means for endoscopic visualization during examination, diagnosis and therapy of the lower urinary tract in conjunction with endoscopic accessories, or as	The Stryker Urology and Gynecology Hardware System is 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, biopsy, incision, and resection of tissue, and/or as the surgeon deems appropriate. The system is 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 tumors • Trans-cervical resection and ablation of the endometrium • Trans-cervical resection of fibroids

Device	Subject Device: Henke-Sass, Wolf Cystoscopes, Hysteroscopes, and Accessories	Predicate Device: K040390 - Stryker Urology and Gynecology Hardware System
	the surgeon deems appropriate. The instruments are intended for use in urological procedures through the minimally invasive approach, by utilizing natural orifices to access the surgical site.	
Regulation Number	884.1690, 876.1500	884.1690
Product Code	FAJ, HIH	HIH, FAJ, FAS, KQT
Working length (± 0.5mm)	269mm – 302mm	269mm – 302mm
Outer diameter (± 0.2mm)	2.7mm – 4.0mm	2.7mm – 4.0mm
Light Source	Xenon, LED	Xenon, LED
Distal tip (outer diameter)	2.7mm – 4.0mm	2.7mm – 4.0mm
Deflection (°)	0°- 70°	0°- 70°

5.8 Conclusion

Based on the above information and all data provided in this submission, the comparison of intended uses, technological characteristics, and non-clinical performance testing demonstrates that the subject devices are substantially equivalent to the predicate device identified in this submission.