June 3, 2025

RZ Medizintechnik GmbH
Daniela Lang
Quality Manager Officer
Unter Haßlen 20/22
Tuttlingen, BW 78532
GERMANY

Re: K243382
Trade/Device Name: RZ Resectoscope System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, FAS, FAJ
Dated: April 17, 2025
Received: April 17, 2025

Dear Daniela Lang:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K243382

Please provide the device trade name(s).

RZ Resectoscope System

Please provide your Indications for Use below.

The resectoscope system devices are intended for use by qualified surgeons for cutting, ablation, vaporization, and/or coagulation of tissue during various endoscopic urological and gynecological electrosurgical procedures.

Please select the types of uses (select one or both, as applicable).

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

RZ Medizintechnik GmbH
Resectoscope System
510(k) Premarket Notification

DATE Prepared:	June 3, 2025
510(K) Submitter:	RZ Medizintechnik GmbH Unter Haßlen 20/22 78532 Tuttlingen Germany Tel: +49-7462-9470-0 E-Mail: daniela.lang@rz-medizintechnik.com
Contact Person	Name: Daniela Lang Position: Quality Manager Tel: +49-7462-9470-22 E-Mail: daniela.lang@rz-medizintechnik.com

1 Device Name

Trade Name:	RZ Resectoscope System
Common Name:	Resectoscope System

2 Classification / Product Code

The RZ Resectoscope System can be classified according to following device name and product codes:

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
RZ Resectoscope System	Hysteroscope and accessories	Obstetrics/ Gynecology	Obstetrics/ Gynecology	HIH, FAJ, FAS	884.1690	II

3 Predicate Device

Predicate Device	510(k) Number	510(k) Holder
HSW Resection Instruments	K173070	Henke-Sass Wolf GmbH

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

4 Device Description

The Resectoscope System from RZ Medizintechnik GmbH consists of a working element, a shaft and an electrode. The Resectoscope System is used during endoscopic surgery in the fields of urology and gynecology with an optical system for visualization. The electrode is inserted into the shaft for use and the shaft is connected to the working element.

The working element and shaft are supplied non-sterile, are intended for multiple use and must be sterilized before each use according to the instructions for use. The electrodes are supplied sterile and are intended for single use only.

To use the Resectoscope System, the electrosurgical unit, pump and light source must be connected to the working element via appropriate connections such as cables, tubing and light guide cables. These components are not part of this 510(K).

5 Indications for Use

The resectoscope system devices are intended for use by qualified surgeons for cutting, ablation, vaporization, and/or coagulation of tissue during various endoscopic urological and gynecological electrosurgical procedures.

6 Technological Characteristics

The technological characteristics of RZ Resectoscope System are the same as the technological characteristics of the predicate device.

6.1 Device Characteristics Table

Company Device Name	RZ Medizintechnik GmbH RZ Resectoscope System (Subject Device)	Henke-Sass Wolf GmbH Resection Instruments (Predicate Device)	Result
Regulation Number	884.1690	884.1690	Substantially Equivalent
Class	2	2	Substantially Equivalent
Product Code	HIH FAJ, FAS	HIH FAJ, FAS	Substantially Equivalent
510(k) number	K243382	K173070	n.a.
Review Panel	Obstetrics/Gynecology	Obstetrics/Gynecology	Substantially Equivalent
Indications for Use	The resectoscope system devices are intended for use by qualified surgeons for cutting, ablation, vaporization, and/or coagulation of tissue during various endoscopic urological and gynecological electrosurgical procedures.	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	Substantially Equivalent

Company Device Name	RZ Medizintechnik GmbH RZ Resectoscope System (Subject Device)	Henke-Sass Wolf GmbH Resection Instruments (Predicate Device)	Result
Working Elements			
Materials	Stainless steel, PTFE	Stainless steel, PTFE	Substantially Equivalent
Diameter	2.0 - 4.0mm	2.0 – 4.0 mm scopes	Substantially Equivalent
Types	Active, passive	Active, passive	Substantially Equivalent
Number of HF Ports	1 for Monopolar 2 for Bipolar	1 for Monopolar 2 for Bipolar	Substantially Equivalent
Electrosurgical mode	Monopolar and Bipolar	Monopolar and Bipolar	Substantially Equivalent
Electrodes			
Shapes	Loops, Knives (needles), Balls, and Rollers	Loops, Knives (needles), Balls, and Rollers	Substantially Equivalent
Sterilization	Provided Sterile (EtO)	Provided sterile (EtO)	Substantially Equivalent
Use	Single Use	Single Use	Substantially Equivalent
Materials	Tungsten, Stainless steel, PTFE	Tungsten, Stainless steel, PTFE	Substantially Equivalent
Insulation Material	PTFE	PTFE	Substantially Equivalent
Diameter	11 Fr. - 27 Fr.	11 Fr. – 27 Fr.	Substantially Equivalent
Electrosurgical Mode	Monopolar and Bipolar	Monopolar and Bipolar	Substantially Equivalent
Sheaths			
Materials	Stainless steel, Ceramic (ZrO2)	Stainless steel, Ceramic (ZrO2)	Substantially Equivalent
Diameter	11Fr. – 28.5 Fr.	19 Fr. – 27 Fr. (inner) 22 Fr. – 28.5 Fr. (outer) 11 Fr. – 27 Fr. (standard)	Substantially Equivalent[A]
Outer sheath tip design	Round drilled flushing holes	Round drilled flushing holes	Substantially Equivalent
Stop Cocks	2, above and below, Or 1 (model dependent)	2, above and below (outer) 1, below (standard)	Substantially Equivalent

Company Device Name	RZ Medizintechnik GmbH RZ Resectoscope System (Subject Device)	Henke-Sass Wolf GmbH Resection Instruments (Predicate Device)	Result
Obturators			
Materials	Stainless steel	Stainless steel	Substantially Equivalent
Diameter	11 Fr. – 27 Fr.	11 Fr. – 27 Fr.	Substantially Equivalent
Tip Design	Rounded tip	Rounded tip	Substantially Equivalent

PTFE: Poly tetrafluoroethylene

A: The RZ Resectoscope system sheaths diameter does not distinguish between inner, outer and standard. The sheaths diameter scope is from 11 to 28.5 Fr. covering the predicate device's scope. This difference does not raise different questions of safety and effectiveness.

7 Device Packaging and Labelling

The non-sterile elements are packed in cardboard boxes with foam inlay for protection of the devices during transportation. The sterile electrodes are primarily packed in blisters with Tyvek lids. Then 6 of such sealed sterilized electrodes are packed in a cardboard box. For safe delivery, the packed blisters (77 cardboard boxes) are placed tightly in the shipping box to obstruct any possible movements. Packaging and transport validations have been performed for the sterile electrodes, in accordance with the following standards:

- ISO 11607-1:2019 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices Part 2 Requirements for forming, sealing and assembly processes

The results of the transport simulation were adequate to verify the suitability of the sterile packaging of the sterile electrodes.

8 Biocompatibility

The resectoscope system materials that come in direct contact with the patient include stainless steel, PTFE, Tungsten and zirconium dioxide (ZrO_2). The subject device materials are identical to the predicate device in formulation, processing, sterilization, and geometry. Therefore, biocompatibility testing from the predicate device can be leveraged to support the biocompatibility of the subject devices.

9 Non-Clinical Performance Testing

No animal studies have been submitted. No clinical studies have been submitted.

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

9.1 Bench Tests

The following bench testing was conducted to verify the performance of the subject devices:

- Visual Inspection
- Leakage Test and Flow Measurement

- Functionality Test/technical tests
- Mechanical force testing

The performed tests have shown that all the products tested have passed the respective tests.

10 Sterilization and Reprocessing

The non-sterile devices need to be reprocessed before first and every consequent use.
The sterile electrodes are sterilized by ethylene oxide (EO) sterilization process performed by a third-party contractor.
Validations have been carried out for manual cleaning and disinfection, automatic cleaning and disinfection and steam sterilization of the non-sterile devices according to the following standards and guidance documents:

- FDA Guidance Document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," Issued March 17, 2015
- ISO 17665-1: 2006, Sterilization of health care products - Moist heat Part 1: Requirement for the development, validation and routine control of a sterilization process for medical devices.

Validation of the EO sterilization for the sterile electrodes has been carried out according to the following standard:

- ISO 11135: 2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

10.1 Shelf Life

The non-sterile elements have no defined shelf-life. As they are reusable, it depends on the wear and tear as well as the usage of the devices.

The sterile electrodes have defined shelf life of 5 years. An accelerated aging test is performed to prove the intended functionality and use of the sterile electrodes in the defined shelf-life period.

Accelerated aging was performed in accordance with ASTM F1980: Standard Guide for Accelerated Aging of Sterile Medical Device Packages and realized a reference temperature of 25°C. The results show that the microbiological barrier properties and sterility are maintained.

11 Substantial Equivalence Summary / Conclusion

Based on the results of non-clinical performance testing, the subject device was demonstrated to be as safe and effective as the predicate device to support a substantial equivalence determination