October 8, 2020

Schoelly Fiberoptic GmbH
% Pamela Papineau, RAC (US, EU, CAN)
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432

Re: K201970
Trade/Device Name: Schoelly Cystoscopes/Hysteroscopes and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a)
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH, FAJ
Dated: July 9, 2020
Received: July 15, 2020

Dear Pamela Papineau:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

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

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)*
K201970

Device Name
Schoelly Cystoscopes/Hysteroscopes and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a)

Indications for Use *(Describe)*
The Schoelly Cystoscopes/Hysteroscopes and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a) 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 anatomy as the surgeon deems appropriate.

The Schoelly Cystoscopes/Hysteroscopes and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a) 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.

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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General Information

Preparation date:	10/08/2020
Owner's Name:	Schoelly Fiberoptic GmbH (Registration: 8043903)
Address:	Robert-Bosch-Str. 1 – 3 79211 Denzlingen Germany
Telephone Number:	+49-7666-980-0
Fax Number:	+49-7666-908-380
Contact Person:	Dr. Sandra Baumann

Subject Device Name:	Schoelly Cystoscopes/Hysteroscopes and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a)
Common/Usual Name:	Cystoscopes/Hysteroscopes and Accessories
Classification Name:	Hysteroscope (And Accessories); Class II; 21 CFR 884.1690
Product Codes:	HIH, FAJ

Predicate Device Name:	Schoelly Cystoscopes/Hysteroscopes and Accessories
Premarket Notification:	K150158, Schoelly Cystoscopes/Hysteroscopes and Accessories

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

Reference Device Name:	E-Line Cysto-Urethroscope and Accessories
Premarket Notification:	K1011496, Wolf E-Line Cysto-Urethroscope and Accessories

Device Description
The Schoelly Cystoscope/Hysteroscope and Accessories comprise several models of rigid endoscopes as well as rigid endoscopic sheaths, obturators, and instrument bridges; the currently marketed system also includes a flexible grasping forceps. This Premarket Notification adds two rigid cystoscope/hysteroscope accessories (optical scissors and optical grasping forceps), both of which have been designed and are intended for use with the currently marketed Schoelly 4mm rigid cystoscope/hysteroscope and 20Fr sheath cleared in K150158. There are no changes to any of the other system components or accessories, nor are there any changes to the Schoelly Cystoscope/Hysteroscope and Accessories indications for use.

The optical scissors and optical grasping forceps accessories both consist of a rigid shaft with an inner lumen that accommodates the 4mm Schoelly Cystoscope/Hysteroscope. The outer diameter and the working length of both accessories are 4.6mm and 266mm, respectively. During application, the scissor or the forceps can be attached to the cystoscope via a simple mechanical locking located at the very proximal portion of the devices. The scissor or grasper is then inserted through a 20Fr Schoelly Cystoscope/Hysteroscope Sheath while being connected to the Schoelly Cystoscope/Hysteroscope. Another mechanical locking mechanism allows the user to lock all three coaxial components (scope, scissor/grasper accessory, and sheath) together. The scissor and grasper accessories incorporate a control handle. Operation of the control handle actuates the distal tip double action jaws via a pull wire mechanism. The optical scissor and grasper accessories are made entirely of stainless steel. The accessories are reusable instruments that are supplied non-sterile.

Indications for Use
The Schoelly Cystoscopes/Hysteroscopes and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a) 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 anatomy as the surgeon deems appropriate.

The Schoelly Cystoscopes/Hysteroscopes and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a) 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.

There are no changes to the indications for use due to the addition of two new accessories.

Substantial Equivalence / Comparison of Technical Characteristics with the Predicate Device
The predicate device system consists of the Schoelly Cystoscopes/Hysteroscopes and Accessories cleared in K150158. A detailed comparison of the subject and predicate device systems is provided in the substantial equivalence table below.

The Richard Wolf E-Line Cysto-Urethroscope and Accessories cleared in K011496 is cited as a reference device in this submission because it represents an example of an integrated rigid endoscope system that includes optical scissors and optical grasping forceps accessories with the same essential design as the new Schoelly optical accessories.

Substantial Equivalence Comparison Table

Attribute	Proposed Schoelly Cystoscopes/Hysteroscopes and Accessories (current submission)	Predicate Device Schoelly Cystoscopes/Hysteroscopes and Accessories (K150158)	Similarities and Differences
Common Name	Cystoscopes/Hysteroscopes and Accessories	Cystoscopes/Hysteroscopes and Accessories	Same
Classification Name	Hysteroscopes and Accessories	Hysteroscopes and Accessories	Same
Device Class	Class II	Class II	Same
Regulation	21 CFR 884.1690	21 CFR 884.1690	Same
Regulation Name	Hysteroscope and accessories	Hysteroscope and accessories	Same
Product Codes	HIH, FAJ	HIH, FAJ	Same

Attribute	Proposed Schoelly Cystoscopes/Hysteroscopes and Accessories (current submission)	Predicate Device Schoelly Cystoscopes/Hysteroscopes and Accessories (K150158)	Similarities and Differences
Indications for Use	The Schoelly Cystoscopes/Hysteroscopes and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a) 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 anatomy as the surgeon deems appropriate. The Schoelly Cystoscopes/Hysteroscopes and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a) 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.	The Schoelly Cystoscopes/Hysteroscopes and Accessories 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 anatomy as the surgeon deems appropriate. The Schoelly Cystoscopes/Hysteroscopes and Accessories 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.	Same
Use Environment	Hospital, clinic, medical office	Hospital, clinic, medical office	Same

Attribute	Proposed Schoelly Cystoscopes/Hysteroscopes and Accessories (current submission)	Predicate Device Schoelly Cystoscopes/Hysteroscopes and Accessories (K150158)	Similarities and Differences
System Components	Cystoscopes (rigid) Sheaths (rigid) Obturators (rigid) Bridges Grasping Forceps (flexible) Rigid optical grasper Rigid optical scissor	Cystoscopes (rigid) Sheaths (rigid) Obturators (rigid) Bridges Grasping Forceps (flexible)	Similar; No changes to and system components cleared in K150158; add two rigid accessories (optical scissors and optical grasping forceps) to be used with existing cystoscopes and sheaths. Reference device system cleared in K011496 provides an example of a rigid cystoscope system that includes rigid optical scissors and grasping forceps accessories similar to those included in this submission.

Attribute	Proposed Schoelly Cystoscopes/Hysteroscopes and Accessories (current submission)	Predicate Device Schoelly Cystoscopes/Hysteroscopes and Accessories (K150158)	Similarities and Differences
Principle of Operation	Rigid cystoscope/hysteroscope and sheath allows access to and visualization of anatomy accessed via natural passages. Couplers/bridges can be used to lock system components together and allow access to the anatomy via the sheath for irrigation and insertion of instruments, e.g. graspers and scissors. Flexible grasping forceps allow for tissue and foreign body manipulation and can be inserted via the couplers/bridges and the annular space between the endoscope and the sheath. The rigid optical scissor and grasper have a central lumen sized to accept the endoscope; the scope and rigid accessory are then inserted through the sheath and allow for cutting and manipulation of tissue and foreign bodies.	Rigid cystoscope/hysteroscope and sheath allows access to and visualization of anatomy accessed via natural passages. Couplers/bridges can be used to lock system components together and allow access to the anatomy via the sheath for irrigation and insertion of instruments, e.g. graspers and scissors. Flexible grasping forceps allow for tissue and foreign body manipulation and can be inserted via the couplers/bridges and the annular space between the endoscope and the sheath.	Similar; No changes to and system components cleared in K150158; add two rigid accessories (optical scissors and optical grasping forceps) to be used with existing cystoscopes and sheaths. Reference device system cleared in K011496 provides an example of a rigid cystoscope system that includes rigid optical scissors and grasping forceps accessories similar to those included in this submission.
Scope Dimensions	2.9mm or 4mm OD x 300-365mm working length	2.9mm or 4mm OD x 300-365mm working length	Same
Scope Optics	0° - 70° Direction of View Standard & wide-angle FOV	0° - 70° Direction of View Standard & wide-angle FOV	Same
Sheath Dimensions	17-25Fr OD x 260.5mm overall length	17-25Fr OD x 260.5mm overall length	Same
Obturator	Blind + visual obturator fits through sheath	Blind + visual obturator fits through sheath	Same
Bridges	Optic, instrument	Optic, instrument	Same
Attachments	Mechanical couplers lock components together	Mechanical couplers lock components together	Same

Attribute	Proposed Schoelly Cystoscopes/Hysteroscopes and Accessories (current submission)	Predicate Device Schoelly Cystoscopes/Hysteroscopes and Accessories (K150158)	Similarities and Differences
Other Accessories	Grasping forceps (flexible). 7Fr OD x 400mm Optical scissors (rigid), 4.6mm OD x 302mm Optical grasper (rigid), 4.6mm OD x 302mm	Grasping forceps (flexible). 7Fr OD x 400mm	Similar; No changes to system components cleared in K150158; add two rigid accessories (optical scissors and optical grasping forceps) to be used with existing cystoscopes and sheaths. Reference device system cleared in K011496 provides an example of a rigid cystoscope system that includes rigid optical scissors and grasping forceps accessories similar to those included in this submission.
Patient-Contacting Materials	Stainless steel, glass, epoxy, AuSn 80/20 brazing material, acetal	Stainless steel, glass, epoxy, AuSn 80/20 brazing material, acetal	Same
Biocompatibility	ISO 10993	ISO 10993	Same
Single Use / Reusable	Reusable	Reusable	Same
Scope Reprocessing	Manual cleaning, high level disinfection, and sterilization	Manual cleaning, high level disinfection, and sterilization	Same; reprocessing validations for new accessories

Differences between the proposed and the predicate devices do not raise different questions of safety and effectiveness.

Non-clinical Performance Testing
The risks associated with the use of the new devices were found acceptable when evaluated in accordance with ISO 14971. Risks and benefits of the predicate device are the same as compared to the proposed ones.

Design verification and validation activities included the following:

- Physical/functional/bench testing (cutting performance, gripping performance, ease of movement, visibility in the endoscope image)
- Biocompatibility testing as per 10993-1:2018, including cytotoxicity, irritation, sensitization, acute systemic toxicity and material mediated pyrogenicity.
- Reprocessing validation, including:
  - Cleaning validation in accordance with AAMI TIR12:2010, and AAMI TIR30:2011 , and FDA Guidance Processing/Reprocessing Medical Devices in Healthcare Settings (dated: June 9, 2017),
  - High level disinfection validation in accordance with ASTM E 1837:96 (2007) and FDA Guidance Processing/Reprocessing Medical Devices in Healthcare Settings (dated: June 9, 2017),
  - Sterilization validation performed in accordance with ISO 17664:2017, ANSI/AAMI/ISO 17665-1:2006 and FDA Guidance Processing/Reprocessing Medical Devices in Healthcare Settings (dated: June 9, 2017), and
  - Performance testing, following reprocessing, including visual inspection, ease of movement and cutting performance.

Conclusion
The Schoelly Cystoscope/Hysteroscope and Accessories with additional Optical Grasping Forceps (51-0575a) and Optical Scissor (51-0576a) meet all the pre-determined acceptance criteria of the testing performed to confirm substantial equivalence to the predicate device