DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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JUL 27 2015

Schoelly Fiberoptic GmbH
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K150158
Trade/Device Name: Schoelly Cystoscopies/Hysteroscope and Accessories
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, FAJ
Dated (Date on orig SE ltr): February 20, 2015
Received (Date on orig SE ltr): February 23, 2015

Dear Mark Job,

This letter corrects our substantially equivalent letter of March 9, 2015.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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)*
K150158

Device Name
Schoelly Cystoscopes/Hysteroscopes and Accessories

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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General Information

Preparation date:	3/4/2015
Owner's Name:	Schoelly Fiberoptic GmbH (Registration: 8043903)
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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
Trade Name:	Schoelly Cystoscopes/Hysteroscopes and Accessories
Common/Usual Name:	Endoscope (Cystoscope, Hysteroscope), Sheath, Obturator, Bridge, Grasping Forceps
Classification Name:	FAJ – Cystoscope and accessories, flexible/rigid 21 CFR 876.1500; Class II HIH- Hysteroscope (and accessories) 21 CFR 884.1690; Class II KOG- Endoscope and/or accessories 21 CFR 876.1500; Class II

Predicate Device Name:	Flexilux II Cystoscope and Hysteroscope
Trade Name:	Flexilux II Cystoscope and Hysteroscope
Common/Usual Name:	Endoscope (Cystoscope, Hysteroscope)
Classification Name:	FAJ – Cystoscope and accessories, flexible/rigid 21 CFR 876.1500; Class II HIH- Hysteroscope (and accessories) 21 CFR 884.1690; Class II

Premarket Notification: K060899, Schoelly Imaging Inc., SE date March 2, 2007

Predicate Device Name:	Stryker Urology and Gynecology Hardware System
Trade Name:	Stryker Urology and Gynecology Hardware System
Common/Usual Name:	Scope, Obturator, Working Element, Sheath, Bridge, Electrode, Albarran Deflector, Timberlake Obturator, Cutting Loop, Roller Ball, Cold Knives, Dilator/Sound/Bougie, Bladder Syringe, Ellik Evacuator, Forceps
Classification Name:	HIH- Hysteroscope (and accessories) 21 CFR 884.1690; Class II FAJ – Cystoscope and accessories, flexible/rigid

21 CFR 876.1500; Class II

FAS - Electrode, electrosurgical, active, urological
21 CFR 876.4300; Class II

KOG- Endoscope and/or accessories
21 CFR 876.1500; Class II

KQT - Evacuator, gastro-urology
21 CFR 876.4370; Class II

Premarket Notification: K040390, Stryker Endoscopy, SE date May 17, 2004

Device Description

The proposed Schoelly Cystoscopes/Hysteroscopes and Accessories comprise several models of rigid endoscopes as well as endoscopic sheaths, obturators, instrument bridges and grasping forceps. The devices 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.

Endoscopes (Cystoscopes/Hysteroscopes):

The endoscopes described in this submission are rigid reusable endoscopes for visualization of the operating site during cystoscopic and hysteroscopic minimally invasive procedures in conjunction with a commercially available light guide, light source, video camera, monitor, and printer.

Light that is created by an external light source is transmitted from the endoscope's light guide connector through the endoscope itself to the tip via a fiber optic system. Images are transferred the other way back through a rigid lens system.

Technical parameters of the Schoelly Cystoscopes/Hysteroscopes that characterize the optical view are the Direction of View (0°-70°) and the Field of View (70°-85°). The image can be displayed by a camera/monitor system which can be connected to the endoscope eyepiece. Models of the Schoelly Cystoscopes/Hysteroscopes differ in diameter and length of the insertion tube (2.9mm; 4mm / 300mm - 365mm). None of the endoscope models have a working channel.

Like other currently marketed rigid cystoscopes and hysteroscopes, all endoscope models have outer surfaces mainly made from metal (Phynox cobalt-nickel-chromium stainless steel alloy, 304 stainless steel) and incorporate fiber optics for light transmission and rigid lenses for image transmission.

Some Schoelly endoscope models have already been cleared for marketing by FDA (K060899) for the same general intended use but with a different material of the

insertion tube and a different bonding material used for the fixation of the plan glass at the endoscope's distal end. Accessories do not have a prior 510(k) clearance.

Sheath:
The endoscopic sheaths included in this submission are rigid reusable instruments with an inner lumen and mainly made from stainless steel; the sheath serves as the most outer part of the whole device setup in cystoscopic or hysteroscopic procedures. The proximal end of the endoscopic sheath has two irrigation ports with integral stopcocks for the introduction and the egress of irrigation media. The distal end of the sheath is cut away in a fenestration to permit the use of working instruments and endoscopes with a Direction of View of more than 0°. Opposite to the fenestration, the sheath is bevelled to facilitate its introduction into natural body orifices (transurethral/transvaginal). The outer diameter of the sheaths in this submission ranges from 17Fr – 25Fr, which are standard sizes used in cystoscopic or hysteroscopic procedures in adults. The sheaths can be used with all endoscopes models, obturators and bridges that are included in this submission.

Obturator:
The obturators included in this submission are rigid reusable instruments with (visual obturators) or without (blind obturators) an inner lumen and mainly made from stainless steel. During application, the obturator can be attached to the endoscopic sheath; it fills the space inside the sheath to provide a smooth surface. The visual obturator has an inner channel that accommodates the endoscope and allows the sheath to be introduced under direct vision. The overall length of the obturator used in conjunction with the sheath complies with the working length of the endoscope.

Bridges:
This submission includes standard endoscope bridges, which are rigid reusable instruments with an inner lumen and mainly made from stainless steel. The evaluation bridges without any accessory port allow the connection of the endoscope to the endoscopic sheath; the single horn bridges include an accessory port with stopcock to allow the insertion of instruments through the inner lumen of the sheath. Both types of bridges are available in a range of lengths for use with the full range of endoscope working lengths.

Grasping forceps:
As with standard endoscopic grasping forceps, the one described in this submission is a flexible forceps solely made from stainless steel and designed for grasping tissue and/or retrieving foreign bodies under endoscopic visualization. It consists of a flexible shaft and a manual proximal control handle. Operation of the proximal control handle actuates the distal tip grasping jaws. The outer diameter and the working length of the grasping forceps comprised in this submission are 7Fr and 400 mm, respectively. The grasping forceps can be introduced into the instrument bridge and moved forward through the inner lumen of the sheath towards the tip.

The Schoelly Cystoscopes/Hysteroscopes and Accessories are delivered in a non-sterile condition and will have CE mark.

Indications for Use

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.

Predicate Device Comparison

The Indications for Use for the proposed Schoelly Cystoscopes/Hysteroscopes and Accessories comprises a subset of the Indications for Use of the predicate Schoelly Flexilux II Cystoscope and Hysteroscope (K060899) and the predicate Stryker Urology and Gynecology Hardware System cleared in K040390.

The predicate Schoelly Flexilux II Cystoscope and Hysteroscope (K060899), which consists only of an endoscope with no accessories, has a very general indications statement referring to use of the instruments for visualization of and therapeutic access to the organs and anatomical structures of interest (hollow organs such as the bladder, uterus, cervical canal). Therefore, the indications statement for the proposed Schoelly Cystoscopes/Hysteroscopes and Accessories was created as an exact subset of the indications for use of the predicate Stryker Urology and Gynecology Hardware System cleared in K040390.

Because the proposed Schoelly Cystoscopes/Hysteroscopes and Accessories system does not include accessories such as knives, scissors, electrodes, etc., the specific examples of uses involving these accessory devices that are present in the Stryker predicate indications statement are not included in the indications statement for this submission.

Technological Characteristics: Similarities and Differences between the Proposed Device and the Predicate Devices

Attribute	Proposed Device	Predicate Schoelly Flexilux II Cystoscope and Hysteroscope (K060899)	Predicate Stryker Stryker Urology and Gynecology Hardware System (K040390)
Endoscope			
Light transmission	Fiber optics	Fiber optics	Fiber optics
Light source	External, connected via light guide to light guide connector	External, connected via light guide to light guide connector	External, connected via light guide to light guide connector
Image transmission	Rigid lenses	Rigid lenses	Rigid lenses
Direction of view	0°-70°	0°-70°	0°-70°
Field of view	70°-85°	70°; 75°	Not known
Image display	Camera/monitor connected to eyepiece	Camera/monitor connected to eyepiece	Camera/monitor connected to eyepiece
Insertion tube working length	300mm - 365mm	302mm	302mm
Insertion tube outer diameter	2.9mm;4mm	2.9mm; 4mm	2.9mm; 4mm
Working channel	None	None	None
Reprocessing	Cleaning (manual and automated), High level disinfection, Sterilization (steam)	Cleaning (manual and automated), Sterilization (steam, EtO, Sterrad, Amsco V-Pro)	Cleaning, Sterilization (steam)
Materials	Stainless steel, stainless steel alloy, glass, glass fibers, adhesive, brazing alloy	Stainless steel, stainless steel alloy, glass, glass fibers, adhesive	Stainless steel, stainless steel alloy, glass, adhesive
Thermal safety	IEC 60601-2-18 compliant	IEC 60601-2-18 compliant	IEC 60601-2-18 compliant
Instruments			
Sheath outer diameter/ Visual Obturator Compatibility	17Fr – 25 Fr	N/A (not scope of K060899)	17Fr - 25Fr
Visual Obturator Total Length	Compatible with sheath and endoscopes with 300mm – 365mm working length	N/A (not scope of K060899)	Compatible with sheath and endoscopes with 302mm working length
Bridg Design	evaluation an single horn bridge	N/A (not scope of K060899)	evaluation, single horn and double horn bridge
Bridge Total Length	Compatible with sheath and endoscopes with 300mm – 365mm working length	N/A (not scope of K060899)	Compatible with sheath and endoscopes with 302mm working length
Forceps Design	Flexible	N/A (not scope of K060899)	Flexible, rigid
Forceps Working Length	40cm	N/A (not scope of K060899)	40cm (flexible)
Forceps Outer Diameter	7Fr	N/A (not scope of K060899)	5Fr; 7Fr; 9Fr
Reprocessing	Cleaning (manual and automated), High level disinfection, Sterilization (steam)	N/A (not scope of K060899)	Cleaning, Sterilization (steam)
Material	Stainless steel, Plastic	N/A (not scope of K060899)	Stainless steel, Plastic

Non-clinical Performance Testing

Performance data demonstrated that the Schoelly Cystoscopes/Hysteroscopes and Accessories have met pre-determined acceptance criteria and are substantially equivalent to predicate devices. The devices are as safe, as effective, and perform as well as or better than the predicate devices. The risks associated with the use of the new devices were found acceptable when evaluated in accordance with • ISO 14971:2012 Medical devices – application of risk management to medical devices. Risks and benefits of predicate devices are the same as compared to the proposed ones.

The following performance testing was conducted for the new devices:

A) Biocompatibility testing as per ISO 10993-1:2009 including:

- Cytotoxicity as per ISO 10993-5:2009
- Sensitization as per ISO 10993-10:2002
- Irritation as per ISO 10993-10:2002
- Systemic toxicity as per ISO 10993-11:2006

B) Temperature testing as per IEC 60601-2-18:2009

C) General performance testing as per ISO 8600-1:2013 and FDA Guidance Hysteroscopes and Gynecologic Laparoscopes - Submission Guidance for a 510(k), issued March 7, 1996 including:

- Field of view
- Direction of view
- Diopters
- Eccentricity
- Size of view
- Vignetting
- Image resolution
- Image distortion

D) Packaging testing as per ISO 2248:1985

E) Reprocessing testing including:

- Manual and automated cleaning efficacy validation as per AAMI TIR12:2010 and AAMI TIR30:2011
- Steam sterilization efficacy validation as per ISO 17664:2004 and ANSI/AAMI/ISO 17665-1:2006
- *For use of devices during cystoscopy:* High level disinfection efficacy validations as per ASTM E 1837:96 (2007)

Devices that have been used for reprocessing testing had underwent multiple soiling-cleaning cycles and surface marring artificially created by scratching with metal tools to simulate end of lifetime use.

Conclusion

The Schoelly Cystoscopes/Hysteroscopes and Accessories meet all the pre-determined acceptance criteria of the testing performed to confirm substantial equivalence to the predicate devices.