



Food and Drug Administration
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February 9, 2016

Schoelly Fiberoptic, GmbH
Dr. Sandra Baumann
Senior Manager Regulatory Affairs
Robert-Bosch-Str. 1-3
79211 Denzlingen
Germany

Re: K151308
Trade/Device Name: Schoelly Nephroscope Set, Schoelly Ultra-Mini Nephroscope Set
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Codes: FGA, FEC, FED
Dated: December 23, 2015
Received: December 28, 2015

Dear Dr. Sandra Baumann,

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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

Indications for Use

510(k) Number (if known)

K151308

Device Name

Schoelly Nephroscope Set

Schoelly Ultra-Mini Nephroscope Set

Indications for Use (Describe)

The Schoelly Nephroscope Set is used for the disintegration and removal / extraction of kidney stones. The stones are removed, under endoscopic control, through percutaneous passages, in conjunction with intracorporeal pneumatic, ultrasound, electrohydraulic or laser lithotripters.

The Schoelly Ultra-Mini Nephroscope Set is used for the disintegration and removal / extraction of kidney stones. The stones are removed, under endoscopic control, through percutaneous passages, in conjunction with laser lithotripters.

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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Section 5 – 510(k) Summary**I. SUBMITTER**

Owner's Name: Schoelly Fiberoptic GmbH (Registration: 8043903)
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 Germany
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 Contact Person: Dr. Sandra Baumann

II. DEVICE

Subject Device Name: Schoelly Nephroscope Family
 Trade Name: Schoelly Nephroscope Set
 Schoelly Ultra-Mini Nephroscope Set
 Common/Usual Name: Nephroscope Set
 Classification Name: FGA – Kit, Nephroscope
 21 CFR 876.1500; Class II
 FEC - Obturator, for Endoscope
 21 CFR 876.1500; Class II
 FED - Endoscopic Access Overtube,
 Gastroenterology-Urology
 21 CFR 876.1500; Class II

III. PREDICATE/REFERENCE DEVICES

Predicate Device Name: Nephroscope Set
 Trade Name: Nephroscope Set
 Common/Usual Name: Nephroscope Set
 Classification Name: FGA - Kit, Nephroscope
 21 CFR 876.1500; Class II
 FEC - Obturator, for Endoscope
 21 CFR 876.1500; Class II
 FED - Endoscopic Access Overtube,
 Gastroenterology-Urology
 21 CFR 876.1500; Class II
 FFL - Ureteral stone dislodger
 21 CFR 876.4680; Class II

Premarket Notification: K994223, Richard Wolf Medical Instruments Corp.,
 SE date June 5, 2000

Recalls: This predicate has not been subject to a design-related recall.

In addition to the Richard Wolf predicate device, the following reference devices were used in this submission to support substantial equivalence and to further outline technological characteristics:

Reference Device Name: 12 Ureteroscopes/Ureterorenoscopes
Trade Name: Compact Operating Fiber Uretero-Renoscopes
Common/Usual Name: Ureteroscopes
Classification Name: FGB – Ureteroscope and accessories, flexible/rigid
 21 CFR 876.1500; Class II
Premarket Notification: K963855, Richard Wolf Medical Instruments Corp,
 SE date April 3, 1997

Reference Device Name: Karl Storz Adult and Pediatric Nephroscope
Trade Name: Karl Storz Adult and Pediatric Nephroscope
Common/Usual Name: Nephroscope
Classification Name: FGA - Kit, Nephroscope
 21 CFR 876.1500; Class II
Premarket Notification: K940594, Karl Storz Endoscopy America,
 SE date September 09, 1994

Reference Device Name: Cook Fiber Optic Bundle and Flexor Deflecting Access
 Sheath
Trade Name: Cook Fiber Optic Bundle and Flexor Deflecting Access
 Sheath
Common/Usual Name: Access Sheath
Classification Name: FED - Endoscopic Access Overtube, Gastroenterology-
 Urology
 21 CFR 876.1500; Class II
 FFS – Image, illumination, fiberoptic, for endoscope
 21 CFR 876.1500; Class II
 FAJ – Cystoscope and accessories, flexible/rigid
 21 CFR 876.1500; Class II
 FGA - Kit, Nephroscope
 21 CFR 876.1500; Class II
 GCJ – Laparoscope, general & plastic surgery
 21 CFR 876.1500; Class II
 FGB – Ureteroscope and accessories, flexible/rigid
 21 CFR 876.1500; Class II
Premarket Notification: K072521, Cook Urological, Inc.,
 SE date November 20, 2007

Reference Device Name: Schoelly Sinuscope
Trade Name: Schoelly Sinuscope
Common/Usual Name: Sinuscope
Classification Name: EOB – Nasopharyngoscope (flexible or rigid)
 21 CFR 874.4760; Class II
Premarket Notification: K142249, Schoelly Fiberoptic GmbH,
 SE date January 27, 2015

IV. DEVICE DESCRIPTION

The proposed Schoelly Nephroscope Family comprises two different application sets: One set for Percutaneous Nephrolithotomy (PCNL) with the trade name “Schoelly Nephroscope Set” and one set for Mini PCNL with the trade name “Ultra-Mini Nephroscope Set”.

Both sets include a rigid, reusable endoscope (nephroscope) that is used in conjunction with a commercially available and approved light guide, light source, video camera, monitor, and printer. Light guide, light source, video camera, monitor, and printer are not included in the scope of delivery and are further not within the scope of this application.

In case of both sets, the nephroscope is accompanied by corresponding accessories to allow for access and passage of the nephroscope and retrieval instruments and for irrigation. Those include compatible endoscopic sheaths, obturators, and bridges.

The Schoelly Nephroscope Set and the Schoelly Ultra-Mini Nephroscope set are delivered in non-sterile conditions and have already obtained CE mark.

Technological Characteristics

Endoscopes (Nephrosopes):

Light that is created by an external light source is transmitted from the nephroscope light guide connector through the nephroscope itself to the tip via a fiber optic system. Images are transferred the other way back through a rigid rod lens system and a fiber optic bundle. The image can be displayed by a camera/monitor system which can be connected to the nephroscope eyepiece.

The main technical parameters that characterize the optical view of the nephrosopes of both application sets are the direction of view (0°-8°) and the field of view (85°). The insertion tube diameter of the nephrosopes is 6Fr - 19Fr and the insertion tube working length is 220mm.

The nephroscope of the Schoelly Nephroscope Set incorporates a working channel with a max. inner lumen capacity of 9Fr and is used in conjunction with an instrument bridge that is mounted to the nephroscope’s proximal end (see “Bridges” Section below).

The nephroscope of the Schoelly Ultra-Mini Nephroscope Set does not have a working channel and is not equipped with an instrument bridge but is accompanied by additional accessories instead. The design of those accessories ensures that if the nephroscope is used in conjunction with them, the setup provides exactly the same functionality. Thus, if assembled appropriately, both application sets incorporate the number of inner lumens required to perform each single step of the intervention and to accommodate auxiliary instruments and irrigation.

Like other currently marketed nephroscopes, all Schoelly configurations have outer surfaces mainly made from stainless steel and further comprise fiber optics for light transmission and rigid rod lenses and fiber optics for image transmission.

Sheaths:

The endoscopic sheaths included in this submission are rigid reusable instruments with inner lumens and mainly made from stainless steel; the sheaths serve as the most outer part of the whole device setup in PCNL and Mini PCNL procedures. The proximal end of the endoscopic sheaths is equipped with one side port for irrigation. The outer diameter of the sheaths in this submission ranges from 11Fr-24Fr to comply with the different nephroscopes and obturators of the proposed Family.

Obturators

The obturators included in this submission are rigid reusable instruments mainly made from stainless steel with an inner lumen sized to accept the needed guide wire (not part of this submission) for correct placement of the sheath in the kidney. During insertion, the obturator fills the space inside the sheath to provide a smooth surface. The overall length of the obturators and their diameter comply with the length and the diameter of the available sheaths.

Bridges:

This submission includes a standard instrument bridge, which is a rigid reusable instrument with an inner lumen and mainly made from stainless steel. It includes ports to allow for insertion of instruments and irrigation through the working channel of the nephroscope of the Schoelly Nephroscope Set. Channels can be sealed with a self-sealing membrane and a stop cock, respectively. It comprises an automatic locking mechanism for easy connection to the proximal end of the nephroscope.

V. INDICATIONS FOR USE

The Schoelly Nephroscope Set is used for the disintegration and removal / extraction of kidney stones. The stones are removed, under endoscopic control, through percutaneous passages, in conjunction with intracorporeal pneumatic, ultrasound, electrohydraulic or laser lithotripters.

The Schoelly Ultra-Mini Nephroscope Set is used for the disintegration and removal / extraction of kidney stones. The stones are removed, under endoscopic control, through percutaneous passages, in conjunction with laser lithotripters.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Indications for Use for the proposed Schoelly Nephroscope Family comprises a subset of the Indications for Use of the predicate device. Since the proposed Schoelly Nephroscope Family is not intended to be used via transurethral access as is the case for the Richard Wolf predicate device, the removal/extraction of bladder stones is not included in the Indications for Use for this submission. Remaining contents of the Indications for Use are identical for the proposed and the predicate device.

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

Attribute	Proposed Nephroscope Family (current submission)	Predicate Richard Wolf Nephroscope Set (K994223)
Endoscope (Nephroscope)		
Light transmission	Fiber optics	Fiber optics
Light source	External, connected via light guide to light guide connector	External, connected via light guide to light guide connector
Image transmission	Rigid rod lenses + fiber optics	Rigid rod lenses, rigid rod lenses + fiber optics
Eyepiece orientation	angled, straight	angled, angled offset
Direction of view	0°-8°	12°-25°
Field of view	85°	95° (Richard Wolf Long Miniature Endoscope)
Image display	Camera/monitor connected via the endoscope eyepiece	Camera/monitor connected via the endoscope eyepiece
Insertion tube working length	220mm	175-225 mm
Insertion tube outer diameter	6Fr-19Fr	15Fr-27Fr
Inner lumen capacity	max.3 Fr – max. 9 Fr	max. 6Fr - max. 12Fr
Single Use / Reusable	Reusable	Reusable
Reprocessing	Cleaning, sterilization (steam)	Cleaning, sterilization (steam, H ₂ O ₂)
Patient contacting materials	Stainless steel, glass, glass fibers, adhesive	Stainless steel, glass, glass fibers, adhesive
Electrical safety	IEC 60601-2-18 compliant	IEC 60601-2-18 compliant
Instruments		
Sheath outer diameter	11Fr-24Fr	15Fr-27Fr
Obturator outer diameter	Compatible with 11Fr-24Fr sheath	Compatible with 15Fr-27Fr sheath
Single Use / Reusable	Reusable	Reusable
Reprocessing	Cleaning, sterilization (steam)	Cleaning, sterilization (steam, H ₂ O ₂)
Patient contacting materials	Stainless steel, silicone, tin/silver alloy	Stainless steel, silicone

VII. PERFORMANCE DATA

The nephroscopes of the proposed Schoelly Nephroscope Family were subjected to temperature, optical parameter and biocompatibility testing.

Temperature testing: the devices were measured for surface temperatures at various locations as long as a steady state temperature was reached using different light sources and found to meet requirements as specified in IEC 60601-2-18.

Optical parameter testing: The devices were tested for all relevant optical parameters, e.g. field of view and direction of view accuracy and found to meet requirements as specified in ISO 8600.

Biocompatibility testing: A series of biocompatibility testing according to ISO 10993, including cytotoxicity, sensitization, irritation, and acute systemic toxicity, demonstrated that the device components that are in contact with the patient are biocompatible.

Reprocessing

The Schoelly Nephroscope Family was the subject of completed reprocessing validations including manual cleaning, automated cleaning and steam sterilization.

Cleaning studies have been performed in accordance with AAMI TIR12:2010 (Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers), AAMI TIR30:2011 (A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable devices), and ANSI/AAMI ST15883-1: 2009 (Washer-disinfectors – Part 1 – General requirements, terms, and definitions and tests).

Sterilization studies have been performed in accordance with ISO 14937:2009 (Sterilization of health care products – General requirements for characterization of sterilizing agent and the development, validation and routine control of a sterilization process for medical devices), ANSI/AAMI ST81:2004 (Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices), ISO 17664:2004 (Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices), and ANSI/AAMI/ISO 17665-1:2006 (Sterilization of health care products – Moist heat - Requirements for the development, validation and routine control of sterilization process for medical devices).

VIII. CONCLUSION

The Schoelly Nephroscope Family meets all the pre-determined testing and acceptance criteria to effectively demonstrate substantial equivalence to the predicate device.