DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 17, 2014

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

Re: K141366
Trade/Device Name: Video Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: November 11, 2014
Received: November 17, 2014

Dear Dr. 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,

Eric A. Mann -S

for Malvina Eydelman
Director
Division of Ophthalmic and Ear,
Nose, and Throat 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)*
K141366

Device Name
Video Bronchoscope System

Indications for Use *(Describe)*
The Schoelly Video Bronchoscope System is intended for use by physicians for diagnostic and therapeutic procedures in nasopharyngeal endoscopy, bronchoscopy, tracheoscopy, and laryngoscopy. The Schoelly Video Bronchoscope is intended to provide visualization via a video monitor.

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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510(k) Summary – K141366

I. SUBMITTER

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

II. DEVICE

Subject Device Name:	Schoelly Video Bronchoscope System
Trade Name:	Schoelly Video Bronchoscope System
Common/Usual Name:	Video Bronchoscope System
Classification Name:	EOQ – Bronchoscope (flexible or rigid) 21 CFR 874.4680; Class II

III. PREDICATE/REFERENCE DEVICES

Predicate Device Name:

Trade Name:	Karl Storz Video Bronchoscope System
Common/Usual Name:	Video Bronchoscope System
Classification Name:	EOQ – Bronchoscope (flexible or rigid) 21 CFR 874.4680; Class II
Premarket Notification:	K071530 (Karl Storz Endoscopy-America, Inc.), SE date August 24, 2007

In addition to the Karl Storz predicate device, the following reference device was used in this submission to support substantial equivalence and address technical comparison of effectiveness of a CMOS imaging sensor (used in the proposed device) vs. a CCD imaging sensor (used in the predicate device) with regards to image quality and resolution.

Reference Device Name:

Trade Name:	Ambu aScope3
Common/Usual Name:	Video Bronchoscope System
Classification Name:	EOQ – Bronchoscope (flexible or rigid) 21 CFR 874.4680; Class II
Premarket Notification:	K130845 (Ambu A/S), SE date November 01, 2013

IV. DEVICE DESCRIPTION

The Schoelly Video Bronchoscope System consists of a flexible and steerable endoscope with an integral working/suction channel and a camera control unit (CCU) for regulation of light intensity and connection to a commercially available monitor, PC, and medical video and image capture unit for image display or image documentation.

The endoscope has outer surfaces mainly made from plastic. The endoscope handle incorporates a control lever to bend the distal tip and a working channel port enabling the insertion of instruments for access to the endoscope tip through the working channel.

For sampling of tracheobronchial secretion or irrigation, the endoscope further incorporates a suction channel with the suction valve port located at the endoscope handle and is accompanied by a suction valve/seal accessory . Suction and working channel converge within the endoscope handle, thus within the endoscope shaft there is only one lumen towards the endoscope tip. The suction power can be adjusted at the suction valve which is rotatable by 360°.

The endoscope further comprises a ventilation system to protect the endoscope shaft during sterilization. The exhaust valve at the endoscope handle can also be used for leakage testing. For this purpose the system is accompanied by a leakage tester and accessories.

LED light sources are integrated in the endoscope handle to illuminate the anatomy under investigation. Light is transmitted through fiberoptic bundles to provide standard dual wide angle illumination as well as a narrower light beam which acts as a focused spot light thereby allowing for an improved visualization of more distal anatomical structures (*DeepVu* illumination). The *DeepVu* function can be activated by pressing a button at the endoscope handle.

The video signal is captured by a CMOS imaging sensor located at the tip of the endoscope and transferred to the CCU. Images can be frozen and stored on a PC or medical video and image capture unit by pressing a button at the endoscope handle.

The Schoelly Video Bronchoscope System is delivered in a non-sterile condition and is already CE marked.

V. INDICATIONS FOR USE

The Schoelly Video Bronchoscope System is intended for use by physicians for diagnostic and therapeutic procedures in nasopharyngeal endoscopy, bronchoscopy, tracheoscopy, and laryngoscopy. The Schoelly Video Bronchoscope is intended to provide visualization via a video monitor.

VI. COMPARISON OF TECHNOLOGCIAL CHARACTERISTICS WITH THE PREDICATE DEVICE AND THE REFERENCE DEVICE

The Karl Storz predicate device is comprised of the same system components (flexible endoscope with working/suction channel and CCU) and an additional light source unit. It has the same principle of operations and identical or almost identical optical parameters and geometric dimensions. It is made out of the same primary materials and the same standards were applied for design verification and validation as compared to the proposed Schoelly Video Bronchoscope System.

Endoscopes of the proposed and the Karl Storz predicate device are based on the same technology for tip bending and ventilation for shaft protection during reprocessing. Light transmission in both devices relies on the same technical principle (light source and fiberoptic bundles). Both the proposed Schoelly and the Karl Storz predicate device have a suction and working channel converging within the endoscope handle and allowing for sampling of liquid, irrigation, and insertion of instruments.

The image signal of the Schoelly device is received by a CMOS imaging sensor; the Karl Storz predicate device utilizes a CCD imaging sensor instead. The Ambu aScope 3 that was cleared by FDA for marketing in K130845 is a Bronchoscope that has exactly the same clinical application as the proposed Schoelly device. In K130845, Ambu A/S demonstrated that the Ambu aScope 3 is substantially equivalent to the Ambu aScope 2 (K110962) with respect to the imaging and illumination system whereas latter comprises exactly the same CMOS imaging sensor at the endoscope's distal tip as the proposed Schoelly Video Bronchoscope
The proposed Schoelly endoscope has LED light sources integrated in the handle; the light source of the Karl Storz predicate Video Bronchoscope is not integrated; an external light source must be connected to the endoscope. The Ambu aScope 3 Bronchoscope uses integrated LED light sources as well and has the same indications for use as the proposed Schoelly Video Bronchoscope System. Light

output that can be obtained with the standard dual wide angle illumination respectively the *DeepVu* illumination of the proposed device is at least as high as values that were obtained for this reference device.

VII. PERFORMANCE DATA

Performance data demonstrated that the Schoelly Video Bronchoscope System has met pre-determined acceptance criteria and is substantially equivalent to the predicate device. The risks associated with use of the new device were found acceptable when evaluated in accordance with ISO 14971. Risks and benefits are the same for both the proposed and predicate devices. Testing has been conducted in accordance with recognized consensus standards to demonstrate electrical safety, EMC, biocompatibility, and optical performance characteristics and to validate the software encompassed in the device.

Reprocessing
The endoscope of the proposed Schoelly Video Bronchoscope System is the subject of completed reprocessing validations including manual cleaning and sterilization; these validations have been conducted in accordance with recognized consensus standards as well as the FDA Draft Guidance Processing/Reprocessing Medical Devices in Healthcare Settings (May 2, 2011).

VIII. CONCLUSION

The Schoelly Video Bronchoscope System meets all the pre-determined testing and acceptance criteria to effectively demonstrate substantial equivalence to the predicate device