K132009

Section 5 – 510(k) Summary

General Information

Preparation date:	06/21/2013
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 CMOS Video Nasopharyngoscope System
Trade Name:	Schoelly CMOS Video Nasopharyngoscope System
Common/Usual Name:	Video Nasopharyngoscope System
Classification Name:	EOB – Nasopharyngoscope (flexible or rigid) 21 CFR 874.4760; Class II
Predicate Device Name:	Karl Storz CMOS Video Rhino-Laryngoscope System Model 11101CM
Trade Name:	Karl Storz CMOS Video Rhino-Laryngoscope System Model 11101CM
Common/Usual Name:	Video Rhino-Laryngoscope System
Classification Name:	EOB – Nasopharyngoscope (flexible or rigid) 21 CFR 874.4760; Class II
Premarket Notification:	K103467 (Karl Storz Endoscopy-America, Inc.), SE date June 28, 2012
Predicate Device Name:	Schoelly Naso-Laryngo-Pharyngoscope
Trade Name:	Schoelly Naso-Laryngo-Pharyngoscope
Common/Usual Name:	Nasopharyngoscope
Classification Name:	EOB – Nasopharyngoscope (flexible or rigid) 21 CFR 874.4760; Class II
Premarket Notification:	K083553 (Schoelly Imaging, Inc.), SE date January 16, 2009

Device Description

The Schoelly CMOS Video Nasopharyngoscope System consists of a flexible and steerable endoscope and a camera control unit (CCU) for regulation of light intensity and connection to a monitor, PC, medical video recorder or printer 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 an integrated LED light source. Light is transmitted through fiberoptic bundles illuminating the anatomy under investigation. The video signal is captured by a CMOS imaging sensor located at the tip of the endoscope shaft and transferred to the CCU.

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

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

Predicate Devices
The Karl Storz predicate device is based on the same technology has the same essential design and dimension characteristics, the same essential optical parameters and the same principle of operations. It is made out of the same primary materials and the same standards were applied and met for design verification and validation as compared to the proposed Schoelly CMOS Video Nasopharyngoscope System.

The Schoelly predicate device differs with respect to the image transfer technology; however this device is built out of identical components/systems for light transmission, angulation of the endoscope's distal tip or ventilation. Further, the manufacturing process for major parts of the endoscope is identical as compared to the endoscope of the proposed Schoelly CMOS Video Nasopharyngoscope System.

Indications for Use
The Schoelly CMOS Video Nasopharyngoscope System may only be used by persons with an appropriate medical qualification and who are acquainted with the rhino/laryngoscopic technique. The endoscope is used for endoscopic diagnosis within the nasal lumens and airway anatomy, and is intended to provide visualization via a video monitor.

The indications for use of the proposed devices are identical to the indications for use of the Karl Storz predicate device.

Non-clinical Performance Testing
Performance data demonstrated that the Schoelly CMOS Video Nasopharyngoscope System has met pre-determined acceptance criteria and is substantially equivalent to the predicate devices. The device is as safe, as effective, and performs as well as or better than the predicate devices. The risks associated with use of the new device were found acceptable when evaluated in accordance with ISO 14971. Risks and benefits of predicate devices are the same as compared to the proposed one.

Testing has been conducted as per IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18, IEC 62304, ISO 8600, and ISO 10993 to address the safety and performance aspects of the device.

Reprocessing
The endoscope of the proposed Schoelly CMOS Video Nasopharyngoscope System is the subject of completed reprocessing validations including manual cleaning, high-level disinfection and STERRAD® 100S sterilization.

Cleaning studies have been performed in accordance with AAMI TIR12:2010 (Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilties: A Guide for Device Manufacturers) and AAMI TIR30:2003 (A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable devices). Devices that have been used for testing had been exposed to extensive clinical use including tip angulation, soiling, and reprocessing to address the FDA Draft Guidance Processing/Reprocessing Medical Devices in Healthcare Settings (dated: May 2, 2011).

Sterilization studies have been performed in accordance with ISO 14937.

Conclusion
The Schoelly CMOS Video Nasopharyngoscope System meets all the pre-determined acceptance criteria of the testing performed to confirm substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

Schoelly Fiberoptic GmbH
c/o Ms. Pamela Papineau
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432

Re: K132009
Trade/Device Name: Schoelly CMOS Video Nasopharyngoscope System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: March 3, 2014
Received: March 5, 2014

Dear Ms. 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. 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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132009

Device Name: Schoelly CMOS Video Nasopharyngoscope System

Indications for Use:

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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH)

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