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

January 27, 2015

Schoelly Fiberoptic Gmbh
% Ms. Pamela Papineau, RAC
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Ave
Ayer, Massachusetts 01432

Re: K142249
Trade/Device Name: Schoelly Sinuscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: December 22, 2014
Received: December 24, 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 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 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

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)*

Device Name
Schoelly Sinuscope

Indications for Use *(Describe)*
The Schoelly Sinuscope is intended for use in otolaryngology and Head and Neck procedures, including rhinology, and endoscopic plastic and reconstructive surgery.

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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K142249 – 510(k) Summary

General Information

Preparation date:	11/24/2014
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 Sinuscope
Trade Name:	Schoelly Sinuscope
Common/Usual Name:	Sinuscope
Classification Name:	EOB – Nasopharyngoscope (flexible or rigid) 21 CFR 874.4760; Class II
Predicate Device Name:	SHARPSITE Ac
Trade Name:	SHARPSITE Ac
Common/Usual Name:	Rigid Rod Lense Endoscope
Classification Name:	EOB – Nasopharyngoscope (flexible or rigid) 21 CFR 874.4760; Class II
Premarket Notification:	K965233, Medtronic Xomed Inc., SE date April 4, 1997

Device Description

The Schoelly Sinuscope is a rigid reusable endoscope for visualization during Otolaryngology-Head and Neck surgery 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.

Schoelly Sinuscopes are manufactured in multiple configurations that differ in insertion tube outer diameter and working length and with respect to optical parameters (direction of view, field of view). Several models of the Schoelly Sinuscope have already been cleared for marketing by FDA (K133682) for the visualization during arthroscopic procedures.

Like other currently marketed sinuscopes, Schoelly Sinuscopes have outer surfaces mainly made from metal (Phynox cobalt-nickel-chromium alloy, 304 stainless steel) and further comprise fiber optics for light transmission and rigid rod-lenses for image transmission.

The Schoelly Sinuscope is delivered in a non-sterile condition and is already CE marked.

Technological Characteristics

Light that is created by an external light source is transmitted from the Sinuscope light guide connector through the Sinuscope itself to the tip via a fiber optic system. Images are transferred the other way back through a rigid rod lens system. Technical parameters of the Schoelly Sinuscopes that characterize the optical view are the Direction of View (0°-70°) and the Field of View (80°-100°). The image can be displayed by a camera/monitor system which can be connected to the Sinuscope eyepiece. The Schoelly Sinuscopes are available in two different configurations for the insertion tube: 4mm diameter, working length 175mm and 2.7mm diameter, working length 110mm. All configurations of the Schoelly Sinuscope do not have any working channel.

A detailed comparison of the technological characteristics with the predicate device is shown in the table below.

Table 5.1
Technological Characteristics of the Proposed Device and the Predicate Device

Attribute	Proposed Device (current submission)	Predicate Device (K965233)
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	Rigid rod lenses
Direction of view	0°-70°	0°-70°
Field of view	80°-100°	80°-100°
Image display	Camera/monitor connected via the endoscope eyepiece	Camera/monitor connected via the endoscope eyepiece
Working channel	none	none
Single Use / Reusable	Reusable	Reusable
Reprocessing	Cleaning, sterilization (steam, STERRAD®)	Cleaning, sterilization (steam, STERRAD®, EtO)
Materials		
- insertion tube (outer surface)	stainless steel, Co-Cr-Ni alloy	stainless steel
- insertion part (distal surface)	stainless steel, glass	stainless steel, glass
- fiber optics	glass fibers	glass fibers
- lens bonding	AuSn brazing alloy, epoxy	epoxy

Attribute	Proposed Device (current submission)	Predicate Device (K965233)
Temperature testing	IEC 60601-2-18 compliant	IEC 60601-2-18 compliant
Packaging	Case with foam insert	Case with foam insert

Indications for Use
The Schoelly Sinuscope is intended for use in otolaryngology and Head and Neck procedures, including rhinology, and endoscopic plastic and reconstructive surgery.

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

Non-clinical Performance Testing
The Schoelly Sinuscope was subjected to temperature, optical parameter, biocompatibility and performance testing with identical acceptance criteria for the Schoelly and the predicate devices. The results of this testing demonstrated that the Schoelly Sinuscope has met pre-determined acceptance criteria and is substantially equivalent to the predicate device. The risks associated with the use of the new device were found acceptable when evaluated in accordance with ISO 14971. Risks and benefits of predicate device are the same as compared to the Schoelly Sinuscope.

Temperature testing: The device was measured for surface temperatures at various locations over time using different light sources and found to meet requirements specified in IEC 60601-2-18 and IEC 60601-1.

Optical parameter testing: The device was tested for all relevant optical parameters and found to meet the minimum requirements defined in internal specifications and as specified in the ISO 8600 series of standards (field of view, direction of view, diopters, image eccentricity, size of view, and vignetting).

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.

Performance testing: Performance testing consisted of measurement of the bonding strength for the Sinuscope distal glass, with comparison to the distal glass bonding strength of the currently marketed predicate device.

Reprocessing
The Schoelly Sinuscope is the subject of completed reprocessing validations including manual cleaning, automated cleaning, steam sterilization, as well as STERRAD® 100S, STERRAD® 100NX and STERRAD® NX 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). Devices that have been used for testing had been undergo multiple reprocessing cycles and surface marring artificially created by scratching with metal tools to simulate end of lifetime use and 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 14937:2009 (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).

Conclusion

The Schoelly Sinuscope meets all the pre-determined acceptance criteria of the testing performed to demonstrate substantial equivalence to the predicate device.