September 6, 2019

Stryker
Jessie Duong
Sr. Staff, Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K191102
Trade/Device Name: Precision S 4K Sinuscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: April 23, 2019
Received: April 25, 2019

Dear Jessie Duong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Precision S 4K Sinuscope

Indications for Use *(Describe)*
The Precision S 4K 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Jessie Duong Senior Staff Regulatory Affairs Specialist Phone: (408) 754-2077 Facsimile: (408) 754-2598 Email: jessie.duong@stryker.com
Date Prepared	April 23, 2019

Subject Device:

Name of Device	Stryker Precision S 4K Sinuscope
Common or Usual Name	Sinuscope
Classification Name	Nasopharyngoscope, 21 CFR 874.4760
Regulatory Class	Class II
Product Code	EOB

Predicate Device:

Name of Device	Schoelly Sinuscope, K142249

Note: The predicate device has not been subject to a design-related recall.

Device Description:

Stryker's Precision S 4K Sinuscopes are tubular optical instruments used to provide a view of internal patient anatomy for examination, diagnosis, and therapy during otorhinolaryngology procedures. The devices are available in a variety of outer diameters and working lengths.

The sinuscopes are reusable devices initially supplied as non-sterile to the user and requiring the user to process (i.e. clean and sterilize) the device for initial use, as well as to reprocess the device after each use. The sinuscope connects to the camera system through a separate coupler. The coupler is provided by the camera system and is not subject of this premarket notification.

The sinuscopes achieve their intended use by guiding light to illuminate and image a patient's internal anatomy, then relaying the image out of the surgical site for processing and display by a separate camera system. The sinuscope's optical system consists of a series of lenses, which includes an objective lens to image the intended object, a relay rod lens system to transmit the image along the working length, and an ocular lens to form the final image size.

Indications for Use:

The Precision S 4K Sinuscope is intended for use in otolaryngology and Head and Neck procedures, including rhinology, and endoscopic plastic and reconstructive surgery.

Comparison of Technological Characteristics with the Predicate Device:

Feature	**Subject Device**	**Predicate Device**
	Precision S 4K Sinuscope	**Schoelly Sinuscope**
Manufacturer	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138 USA	Schoelly Fiberoptic GmbH Robert-Bosch-Str. 1-3 79211 Denzlingen Germany
Submission Reference	Current Submission	K142249
Indications for Use Statement	The Precision S 4K Sinuscope is intended for use in otolaryngology and Head and Neck procedures, including rhinology, and endoscopic plastic and reconstructive surgery	The Schoelly Sinuscope is intended for use in otolaryngology and Head and Neck procedures, including rhinology, and endoscopic plastic and reconstructive surgery
Image Transmission	Rigid rod lenses	Rigid rod lenses
Outer diameter	4.0mm, 3.1mm	4.0mm, 2.7mm
Working Length	125mm – 180mm	110mm – 175mm
DOV	0°-70°	0°-70°
FOV	80°-105°	80°-100°
Key Patient-Contacting Materials	Stainless Steel, Optical Glass, Glass Fibers	Stainless Steel, Optical Glass, Glass Fibers, Co-Cr-Ni Alloy
Single Use or Reusable	Reusable	Reusable
Cleaning	Manual and Automated	Manual and Automated
Disinfection	Manual and Automated	Not available
Sterilization Methods	Autoclave, Steris VPRO, APS Sterrad	Autoclave, APS Sterrad
Sterility Assurance Level	10^{-6}	10^{-6}

Performance Testing:

The following performance data were provided in support of the substantial equivalence determination.

Test Category	Applicable Standards / Guidance	Result
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 FDA Guidance: Use of International Standard ISO 10993-1	Pass
Cleaning	AAMI TIR30 AAMI ST15883-5	Pass
Disinfection	AAMI TIR 12 ISO 15883-2	Pass
Sterilization	ISO 14937 ANSI/AAMI ST79 ANSI/AAMI ST58 ISO 17665-1	Pass
Electrical Safety & Temperature Testing	IEC 60601-1 IEC 60601-2-18	Pass
Packaging Qualification	ASTM D4149	Pass
Optical Performance	ISO 8600-1	Pass
Design Validation	AAMI/ANSI HE75 AAMI/IEC 62366 FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices	Pass
Performance – Bench	In accordance with device performance specifications	Pass

Conclusions:

The Precision S 4K Sinuscope is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. There are no new issues of safety and/or effectiveness introduced by the Precision S 4K Sinuscope when used as instructed.