June 4, 2026

Stryker Endoscopy
Divya Sekar
Senior Principal, Regulatory Affairs Specialist
5900 Optical Ct.
San Jose, California 95138

Re: K253602
Trade/Device Name: Precision S 4K Sinuscope
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG, EOB
Dated: May 8, 2026
Received: May 8, 2026

Dear Divya Sekar:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.06.04 16:29:16 -04'00'

for Jaime Raben, Ph.D.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253602

Please provide the device trade name(s).

Precision S 4K Sinuscope

Please provide your Indications for Use below.

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 Precision S 4K Sinuscope is also intended for use in minimally invasive cranial neurosurgery in adults and pediatric patients and endonasal skull base surgery in adults and pediatric patients > 6 years of age.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R Part 807.92(c).

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Divya Sekar Senior Principal, Regulatory Affairs Specialist Email: divya.sekar@stryker.com Phone: 408-754-2473
Date Prepared	November 17, 2025

Subject Device:

Name of Device:	Precision S 4K Sinuscope
Common or Usual Name:	Sinuscope
Classification Name:	Neurological Endoscope [1] (21 C.F.R. §882.1480) Nasopharyngoscope (flexible or rigid) and accessories[2] (21 CFR §874.4760)
Regulatory Class:	Class II
Product Code:	GWG[1]
Subsequent Product Code:	EOB[2]
510(k) Review Panel:	Neurology

[1]When intended for use in neurosurgery procedure.
[2]When intended for use in otolaryngology procedure.

Predicate Device(s):

Precision S 4K Sinuscope	K211202 (primary), K191102

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 surgical procedures. The Precision S 4K Sinuscope transmits visible and near-infrared light to illuminate and image the anatomy, then relaying the image out of the surgical site for processing and display.

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.

The Precision S 4K Sinuscope is also intended for use in minimally invasive cranial neurosurgery in adults and pediatric patients and endonasal skull base surgery in adults and pediatric patients > 6 years of age.

Comparison of Technological Characteristics with the Predicate Device:

Feature	Subject Device Precision S 4K Sinuscope	Predicate Device Precision S 4K Sinuscope
Manufacturer	Stryker Endoscopy	Same as subject device
Submission Reference	Current Submission	K211202 (primary), K191102
Intended Use	Endoscopic illumination and imaging during endoscopic procedures.	Same as subject device
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 Precision S 4K Sinuscope is also intended for use in minimally invasive cranial neurosurgery in adults and pediatric patients and endonasal skull base surgery in adults and pediatric patients > 6 years of age.	Same as subject device
Design		
Operating Principles	Transmission of light to illuminate and image procedures, then relays the image out of the surgical site for processing and display.	Same as subject device
Image Transmission	Rigid rod lenses	Same as subject device
Transmission Spectrum	Visible and Near-infrared	Same as subject device
Outer Diameter (OD)	4.0mm, 3.1mm	Same as subject device
Working Length (WL)	125mm – 180mm	Same as subject device
Direction of View (DOV)	0°-70°	Same as subject device
Field of View (FOV)	80°	80° for 3.1mm Sinuscope 105° for 4.0mm Sinuscope
Depth of Field	7mm – 35mm	Same as subject device
Optional Accessories	Precision S HydroFlow Cleaning Sheath (available for 155mm – 180mm WL Sinuscopes)	N/A – No optional accessory

Feature	Subject Device	Predicate Device
	Precision S 4K Sinuscope	**Precision S 4K Sinuscope**
Materials		
Working Length (patient-contacting)	Stainless steel	Same as subject device
Distal Tip (patient-contacting)	Stainless steel, optical glass, epoxy, glass fibers, solder, copper alloy	Same as subject device
Main body (non-patient contacting)	Stainless steel, TiAlOx	Same as subject device
Eyepiece (non-patient contacting)	Polyetheretherketone (PEEK)	Same as subject device
Processing		
Single Use or Reusable	Reusable	Same as subject device
Cleaning	Manual and Automated	Same as subject device
Disinfection	Automated	Same as subject device
Sterilization	Steam (Autoclave), Hydrogen Peroxide (Steris, Sterrad)	Same as subject device
Sterility Assurance Level	10^{-6}	Same as subject device

Performance Data:

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

Test	Method	Result
Biocompatibility	In accordance with FDA-recognized voluntary consensus standard ISO 10993-1:2018 (2-258)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-5:2009 (2-245)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-10:2021 (2-296)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-11:2017 (2-255)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-23:2021 (2-291)	Pass
Cleaning, Disinfection & Sterilization (Reprocessing)	In accordance with AAMI TIR12:2020 /(R)2023 (14-602)	Pass
	In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST98:2022 (14-583)	Pass
	In accordance with ISO 15883-1:2006 + A1:2014	Pass
	In accordance with ISO 15883-2:2006	Pass
	In accordance with ISO 15883-5:2021	Pass
	In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST79:2017 + A1:2020, A2:2020, A3:2020, A4:2020 (14-562)	Pass

Test	Method	Result
	In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST58:2024 (14-607)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 17664-1:2021 (14-578)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 17665:2024 (14-601)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 22441:2022 (14-586)	Pass
Electrical Safety	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1:2020 (19-49)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 60601-2-18:2009 (9-114)	Pass
Packaging	In accordance with FDA-recognized voluntary consensus standard ASTM D4169:2022 (14-576)	Pass
Optical Performance	In accordance with FDA-recognized voluntary consensus standard ISO 8600-1:2015 (9-110)	Pass
Performance – Bench	Sinuscope - Comparative optical performance testing to currently legally marketed predicate device: Depth of Field, Modulated Transfer Function (MTF), Vignetting, Illumination, Optical Transmission, Field of View (FOV), Apparent Field of View (AFOV), Optical Train Concentricity.	Pass
	Sinuscope - Fiber Transmission and NIR Wavelength Transmission.	Pass
	Sinuscope - Sharp Edge Inspection and Distal Tip Geometry	Pass
	Sinuscope - In Focus / Out of Focus Particulates	Pass
	Sinuscope – Visual Verification of Transmission Capabilities	Pass
	Sinuscope / Cleaning Sheath - Design Validation	Pass
	Sinuscope / Cleaning Sheath - Compatibility and Cleaning Performance	Pass
	Cleaning Sheath - Fiber transmission, Illumination homogeneity and Bending stiffness	Pass

NOTE: Precision S 4K Sinuscope does not require animal or clinical testing to support the determination of substantial equivalence.

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.