December 1, 2020

Stryker Endoscopy
Christie Samsa
Principal Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K202659
Trade/Device Name: Stryker Arthroscopes
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: October 30, 2020
Received: November 2, 2020

Dear Ms. Samsa:

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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K202659

Device Name
Stryker Arthroscopes

Indications for Use *(Describe)*
Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporal mandibular joint, ankle elbow, and feet (plantar fascia release).

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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510(k) Summary

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Christie Samsa, ME, RAC Principle Regulatory Affairs Specialist Phone: (978) 500-1303 Email: christie.samsa@stryker.com
Date Prepared	September 11, 2020

Subject Device:

Name of Device	Stryker Arthroscopes
Common or Usual Name	Stryker Arthroscopes
Classification Name	Arthroscope, 21 CFR 888.1100
Regulatory Class	Class II
Product Code	HRX

Predicate Device:

Name of Device	Precision Ideal Eyes® 4K Arthroscopes, K093677 & K183470

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

Device Description:

Stryker Arthroscopes are tubular optical instruments used to provide a view of internal patient anatomy for examination, diagnosis, and therapy during arthroscopic procedures. The devices are available in a variety of outer diameters and working lengths.

The arthroscopes are reusable devices initially supplied as non-sterile to the user and requiring the user to process the device for initial use, as well as to reprocess the device after each use. The devices are available in an eyepiece and a C-Mount design. The eyepiece arthroscopes connect to the camera system through a separate coupler; the C-Mount arthroscopes connect directly to the camera system through an integrated coupler.

Stryker's arthroscopes achieve their intended use by guiding light to illuminate and image an arthroscopic joint, then relaying the image out of the surgical site for processing and display by a separate camera system. The arthroscopes' 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:

Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporal mandibular joint, ankle elbow, and feet (plantar fascia release).

Comparison of Technological Characteristics with the Predicate Device:

Feature	**Subject Device**	**Predicate Device**
	Stryker Arthroscopes	**Stryker Arthroscopes**
Manufacturer	Stryker Endoscopy	Same as subject device
Submission Reference	Current Submission	K093677
Indications for Use Statement	Stryker arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporal mandibular joint, ankle elbow, and feet (plantar fascia release).	Same as subject device
Operating principles	Transmission of light to illuminate and image an arthroscopic joint, then relaying the image out of the surgical site for processing and display.	Same as subject device
Outer diameter	4mm, 2.9mm, 2.7mm, 2.4mm, 1.9mm	Same as subject device
Working Length	200mm, 165mm, 140mm, 120mm, 75mm, 72mm, 58mm	Same as subject device
DOV	0°, 30°, 45°, 70°, and 30° reverse cant	Same as subject device
FOV	105°, 80°, 65°	Same as subject device
C-mount coupler seal	U-cup seal	Quad ring seal
Key Patient-Contacting Materials	Stainless Steel, Optical Glass, Glass Fibers	Same as subject device
Single Use or Reusable	Reusable	Same as subject device
Cleaning	Manual and Automated	Same as subject device
Disinfection	Manual and Automated	Same as subject device
Sterilization Methods	Autoclave, Steris VPRO, APS Sterrad	Same as subject device
Sterility Assurance Level	10^{-6}	Same as subject device

Performance Testing:

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

Test	Method	Result
Electrical Safety	IEC 60601-1 IEC 60601-2-18	PASS
Packaging	ASTM D4169	PASS
Visual Inspection	ISO 8600-1	PASS
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11	PASS
Cleaning and Disinfection	AAMI TIR 12 AAMI TIR 30 ISO 15883-5 ISO 15883-2	PASS
Sterilization	AAMI ST79 AAMI ST58 ISO 17665-1 ISO 14937	PASS
Performance – Bench	Needle Torque	PASS
	Needle Torque – Dynamic Torque	PASS
	Focus Ring Torque	PASS

Conclusions:

The Stryker Arthroscope 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 Stryker Arthroscope when used as instructed.