September 4, 2020

Arthrex, Inc.
Heli Chambi Infantas
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K201134
Trade/Device Name: Arthrex NanoScope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 4, 2020
Received: August 5, 2020

Dear Heli Chambi Infantas:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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

Arthrex NanoScope System

Indications for Use *(Describe)*

The Arthrex NanoScope system is intended to be used as an endoscopic video camera in a variety of endoscopic diagnostic and surgical procedures, including but not limited to: orthopedic, spine, laparoscopic, urologic, sinuscopic, and plastic surgical procedures. The device is also intended to be used as an accessory for microscopic 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.

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510(k) Summary

Date Prepared	September 4, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Heli F Chambi Infantas Regulatory Affairs Associate 1-239-643-5553, ext. 71263 Heli.chambiinfantas@arthrex.com
Name of Device	Arthrex NanoScope System
Common Name	Endoscopic Video Camera System
Product Code	GCJ, HRX
Classification Name	21 CFR 876-1500: Endoscope and accessories
Regulatory Class	II
Predicate Device	K190645 – Arthrex NanoScope System K180766 – Endiscope Cervical
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to add spine as an additional anatomical location for the Arthrex NanoScope System indications for use. This 510K is also submitted to extend the shelf life of the product sterile component from 6 to 18 months and to present labeling changes for storage conditions.
Device Description	The Arthrex NanoScope System provides image processing and digital documentation for endoscopic procedures. The system utilizes a handpiece which provides distal LED illumination to the surgical site using a fiber optic bundle surrounding a high-resolution camera sensor.
Indications for Use	The Arthrex NanoScope System is intended to be used as an endoscopic video camera in a variety of endoscopic diagnostic and surgical procedures, including but not limited to: orthopedic, spine, laparoscopic, urologic, sinuscopic, and plastic surgical procedures. The device is also intended to be used as an accessory for microscopic surgery.
Substantial Equivalence Summary	The Arthrex NanoScope System is substantially equivalent to the predicate devices in which the basic design features and intended users are the same. Nonclinical (bench) testing was performed to demonstrate substantial equivalence to the predicate regarding thermal safety, electrical safety, optical performance, environmental conditions, power requirements, image capture, and video output and resolution. An engineering analysis was performed to address the substantial equivalence of the field of view and the working diameter compared to the predicate device. Accordingly, Arthrex believes that the Arthrex NanoScope System is substantially equivalent to its original K190645 clearance and to the Elliquence Endiscope Cervical system cleared under K180299.
Conclusion	The proposed Arthrex NanoScope System is substantially equivalent to the predicate device in which the basic design feature and intended use are the same. The visualization for the intraoperative site during spinal endoscopic procedures and minimally invasive surgery does not deviate from the current endoscopic visualization intended use and application originally cleared under K190645. Any differences between the proposed device and the predicate device are considered minor and do not raise questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate device.