



May 16, 2025

Arthrex, Inc.
Lai Saeteurn
1370 Creekside Blvd.
Naples, Florida 34108

Re: K243602
Trade/Device Name: Arthrex Spine Endoscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: April 16, 2025
Received: April 16, 2025

Dear Lai Saeteurn:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

JESSE MUIR -S Digitally signed by JESSE
MUIR -S
Date: 2025.05.16 10:30:22
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Jesse Muir, 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

Indications for Use

Submission Number (if known)

K243602

Device Name

Arthrex Spine Endoscope

Indications for Use (Describe)

The Arthrex Spine Endoscope is indicated for use to provide visualization during spinal endoscopic procedures and minimally invasive 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	May 14, 2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Lai Saeteurn Phone: 239-643-5553 Email: Lai.Saeteurn@Arthrex.com
Trade Name	Arthrex Spine Endoscope
Classification Name	21 CFR 888.1100: Arthroscope 21 CFR 876.1500: Endoscope and accessories
Product Code	HRX, GCJ
Common Name	Spinal Endoscope
Regulatory Class	Class II
Primary Predicate Device	K130778 RZ Medizintechnik Cervical Endoscopes
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Spine Endoscope.
Device Description	The Arthrex Spine Endoscope is a rigid endoscope that contains a rod lens system and optical fibers. When connected to a compatible Arthrex light guide cable and camera system, the endoscope provides image and light transmission, allowing for visualization and illumination of a surgical site. The endoscope includes an ocular funnel, a working channel, inflow and outflow ports, and a connector with adapters for fiber optic light cables. It is available with a 15° or 30° direction of view, outer diameter of 6.3 mm, 7 mm, or 10 mm, and working length of 130 mm, 139 mm, or 181 mm. The Arthrex Spine Endoscope is a reusable multi-patient use device.
Indications for Use	The Arthrex Spine Endoscope is indicated for use to provide visualization during spinal endoscopic procedures and minimally invasive surgery.
Performance Data	Non-clinical bench testing was developed and performed on the Arthrex Spine Endoscope to confirm the device meets product requirements and device specifications. These include biocompatibility testing, cleaning/disinfection and reprocessing validation, design verification, and electrical, mechanical, and thermal (EMT) safety evaluation. The testing methods used and acceptance criteria are comparable to the predicate device.
Technological Comparison	The Arthrex Spine Endoscope and predicate device have the same intended use, indications for use, and technological characteristics (i.e., design, materials, principle of operation, manufacturing and packaging processes, cleaning, disinfection and reprocessing requirements).
Conclusion	All verification activities were successfully completed to confirm the subject device meets product requirements and design specifications established for the device.

The Arthrex Spine Endoscope did not require animal testing or human clinical studies to support the determination of substantial equivalence.

Based on the same intended use, indications for use, technological characteristics, and successful completion of non-clinical bench testing, the Arthrex Spine Endoscope is as safe and as effective as the legally marketed predicate device. Any differences between the subject device and predicate device are considered minor and do not raise different questions concerning safety and effectiveness.
