July 30, 2025

HydroCision, Inc.
Mark Lewis
Vice President Operations and Regulatory Affairs
267 Boston Road
Suite 28
North Billerica, Massachusetts 01862

Re: K241990
Trade/Device Name: HydroCision SpineSite System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: July 2, 2025
Received: July 2, 2025

Dear Mark Lewis:

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: 2025.07.30 12:39:54 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241990

Device Name

HydroCision SpineSite System

Indications for Use *(Describe)*

The HydroCision SpineSite System is intended to be used as a single-use endoscopic video camera in a variety of endoscopic diagnostic and surgical procedures for spine applications. 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.

510(k) Summary

HydroCision SpineSite System

Date Prepared: July 29, 2025

Submitter Information

Submitter: HydroCision™, Inc.
Address: 267 Boston Rd,
North Billerica, MA 01862

Contact Person: Mr. Richard Lytle
Chief Executive Officer
Phone: +1 (630) 779-1723
Email: rlytle@hydrocision.com

Device Information

Device Proprietary Name:	HydroCision SpineSite System
Common Name:	Arthroscope
Device Classification:	Class II
Regulation:	21 CFR 880.1100
Classification Name:	Arthroscope and accessories
Classification Panel:	Orthopedic
Product Code:	HRX
Predicate Device:	Arthrex Nanoscope System, K201134 Product Codes: GCJ, HRX Classifications: 876.1500 and 888.1100

Purpose of Submission:

The purpose of this Traditional 510(k) submission is to gain regulatory clearance per section 510(k) of the Federal Food, Drug and Cosmetic Act for the HydroCision SpineSite System, consisting of a sterile, single-use, disposable endoscope and a reusable, non-sterile capital equipment Video Processing Unit (VPU).

Device Description:

The HydroCision SpineSite System is comprised of (i) sterile disposable endoscope and (ii) reusable Video Processing Unit (VPU). The HydroCision SpineSite System provides illumination, image processing and digital documentation for endoscopic procedures. The HydroCision SpineSite System is not suitable for use in the MR environment.

The SpineSite Endoscope provides distal LED illumination via LEDs surrounding a high-resolution video sensor. The SpineSite Endoscope contains a working channel for the passage of micro instrumentation to the surgical site. The SpineSite Endoscope is provided sterile, via ethylene oxide sterilization.

The SpineSite Endoscope is designed to be connected to the SpineSite VPU via a proprietary edge card connector which provides power to the endoscope and supports video processing capability. The SpineSite VPU is powered via connection to an external wall outlet via a 12V power adapter.

Indications for Use:

The HydroCision SpineSite System is intended to be used as a single-use endoscopic video camera in a variety of endoscopic diagnostic and surgical procedures for spine applications. The device is also intended to be used as an accessory for microscopic surgery.

Performance Testing:

The following non-clinical testing was performed on the HydroCision SpineSite System to confirm the device meets product specification and performance requirements:

- Biocompatibility per ISO 10993-1
- Design verification/validation to mechanical and optical specifications
- Electrical, Mechanical and Thermal (EMT) safety testing per IEC 60601-1, IEC 60601-2-18
- Human Factors/ Usability per IEC 60601-1-6
- Electromagnetic compatibility testing per IEC 60601-1-2
- Software validation

Substantial Equivalence Summary:

The HydroCision SpineSite System is substantially equivalent in intended use, technological design, performance and principles of operation to the predicate device; Arthrex Nanoscope System (K201134). Both systems include the same principal components- (i) a single use, disposable endoscopic camera system and (ii) video processing technology. The disposable endoscope component of both devices consists of a plastic handle, LED light transmission, image processing and digital image documentation capability. The HydroCision SpineSite System has the same intended use as the predicate device as a video camera system providing illumination and visualization at the surgical site. The indications for use for the HydroCision SpineSite Endoscope System represent a subset of the cleared indications for the predicate Arthrex Nanoscope System. As a subset of the indications for the cleared device, this difference does not raise any new risks or issues related to safety or efficacy.

The HydroCision SpineSite System and the predicate device consist of the same technology and are sterilized with same acceptable method. Both the devices are fabricated of biocompatible materials and comply with applicable electrical safety standards.

Below is a comparison table that provides a top-level overview of the substantial equivalent comparison between proposed and predicate devices.

Comparative Characteristics	Proposed Device: HydroCision SpineSite System	Predicate Device: Arthrex Nanoscope System (K201134)
Single Use	SpineSite Endoscope is single-use disposable	Nanoscope is single-use disposable

Comparative Characteristics	Proposed Device: HydroCision SpineSite System	Predicate Device: Arthrex Nanoscope System (K201134)
	SpineSite Video Processing Unit – reusable, does not enter sterile field	Nanoscope Console – reusable, does not enter sterile field
Principle System Components (Sterile, Disposable, Single Use)	SpineSite Endoscope	Nanoscope
Principle System Components (Reusable)	SpineSite Video Processing Unit	Nanoscope Control Unit
Sterilization	SpineSite Endoscope Supplied Sterile, EO Sterilization	Nanoscope Supplied Sterile, EO Sterilization
Electrical Safety		
Compliance to applicable Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18
Materials		
Biocompatibility of Materials	Meets ISO 10993-1 requirements for tissue/bone/dentin contact of limited duration (<24 hrs)	Meets ISO 10993-1 requirements for tissue/bone/dentin contact of limited duration (<24 hrs)
Technical Features/Design - Endoscope		
Optical Resolution	400 × 400 pixels	400 × 400 pixels
Field of View	120°	120°
Angle of View	0°	0°
Depth of field	5 mm-50 mm	3 mm × 100 mm
Working Length	200 mm	125 mm, 180 mm, and 250 mm lengths
Overall Diameter	5.0 mm	Scope diameter 1.9mm; utilizes accessory scope sheath of up to 3.4 mm diameter
Packaging Description	Blister tray, Tyvek lid seal, Tyvek pouch, unit box.	Sealed mylar/Tyvek pouch or a PETG tray with a sealed Tyvek lid.
Technical Features/Design – Video Processing Unit		
Control Unit	Reusable video processing unit	Reusable 13 in HD monitor/console
Endoscope connection	Via edge card connector from endoscope	Via edge card connector from endoscope
Output connectors	HDMI, USB ports	Ethernet, HDMI, USB ports
Power Source	110 V via 12 V power adapter	Universal input 110/240V medical grade - 19 V /110 W
Audio capability	n/a	microphone
Internet Connectivity	n/a	Ethernet and Wi-FI

Comparative Characteristics	Proposed Device: HydroCision SpineSite System	Predicate Device: Arthrex Nanoscope System (K201134)
Image Display	User provided monitor	11.5 inches x 6.5 inches

Conclusion:

The proposed HydroCision SpineSite System is substantially equivalent to the predicate Arthrex Nanoscope System (K201134). The safety and effectiveness of the HydroCision SpineSite System are adequately supported by the non-clinical performance data, substantial equivalence information, and comparison of design characteristics provided within this premarket notification. Any differences between the proposed device and the predicate device are considered minor and do not raise new questions concerning safety or effectiveness.

Based on intended use, technological characteristics and the summary of data submitted in this premarket notification, the HydroCision SpineSite System is determined to be substantially equivalent to the predicate Arthrex Nanoscope device.