May 26, 2026

Clarus Medical, LLC
% Alan Vanhouten
Quality & Regulatory Consultant
Alan VanHouten Biomedical Consultant
916 Ridgecrest Drive
Carver, Minnesota 55315

Re: K252790
Trade/Device Name: Digital ClarusScope System and Digital NeuroPEN System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: April 24, 2026
Received: April 24, 2026

Dear Mr. Vanhouten:

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2026.05.26 13:26:11 -04'00'

Jesse Muir, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252790

Device Name
Digital ClarusScope System
Digital NeuroPEN System

Indications for Use *(Describe)*
The Digital ClarusScope System and Digital NeuroPEN System are intended for accessing and visualizing the interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures on the ankle, elbow, wrist, and spine.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

A. General Information:

Submitter: Clarus Medical, LLC
13355 10th Ave North
Minneapolis, MN 55441
763-525-8403

Contact: Alan VanHouten
Quality & Regulatory Consultant
Alan VanHouten Biomedical Consulting
alanvanhouten@hotmail.com

Date Prepared: May 19, 2026

B. Trade Name:

Digital ClarusScope System
Digital NeuroPEN System

Common Name: arthroscope
Product Code: HRX
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Class: II

C. Predicate Device:

510(k) Number	Description
K143705	NeedleCam HD™ Visualization System

D. Reference Device:

510(k) Number	Description
K240535	Digital ClarusScope System, and Digital NeuroPEN System

E. Device Description:

System level description;

The Digital ClarusScope System and Digital NeuroPEN System are arthroscopes which provides a light source, camera, and HDMI output for visualization. Irrigation is provided for flushing during the procedure. The working channel facilitates the use of tools necessary for arthroscopic procedures (Digital ClarusScope versions only). The Digital ClarusScope and Digital NeuroPEN are intended to be used with the non-sterile, reusable Clarus Digital Control Module with standard HDMI video output. The proximal end of the Digital ClarusScope and Digital NeuroPEN terminate in two fittings: the endoscope connector attaches to the Clarus Digital Control Module, which interfaces to a standard off-the-shelf HDMI video monitor which is not provided by Clarus and is not part of this 510(k) application; the other fitting is an irrigation extension tube with a female Luerlock connector.

510(k) Summary

The Digital NeuroPEN Model number: 2120-515
Description: The Digital NeuroPEN is a sterile, single use, spinal endoscopes with a distal tip camera, light source, and irrigation channel. The Digital NeuroPEN is intended to be used with the non-sterile, reusable Clarus Digital Control Module with standard HDMI video output. The proximal end of the Digital NeuroPEN terminates in two fittings: the endoscope connector attaches to the Clarus Digital Control Module, which interfaces to a standard HDMI video monitor; the other fitting is an irrigation extension tube with a female Luer lock connector.

The Digital ClarusScope Model number: 2100-500
Description: The Digital ClarusScope is a sterile, single use, arthroscope with a distal tip camera, light source, irrigation channel and working channel. The Digital ClarusScope is intended to be used with the non-sterile, reusable video Digital Control Module with standard HDMI output. The proximal end of the Digital ClarusScope terminates in two fittings: the endoscope connector attaches to the Digital Control Module, which interfaces to an HDMI monitor; the other fitting is an irrigation extension tube with a female Luerlock connector.

The Digital Control Module Model number: 5190-500
Description: The Digital control Module is powered by a medical grade DC power adapter provided with the system. The video image captured from the endoscope is transferred through the Digital Control Module and is output using a standard HDMI video cable which connects to a standard video monitor providing a digital image.
The Digital Control Module provides controls for variable illumination level with level indicator along with control for white balance and system.

F. Indications For Use:

The Digital ClarusScope System and Digital NeuroPEN System are intended for accessing and visualizing the interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures on the ankle, elbow, wrist, and spine.

G. Comparison to Predicate and reference Devices:

The predicate and subject devices have similar indications and similar construction. The Digital ClarusScope and Digital NeuroPEN System are substantially equivalent to the predicate device in terms of design, materials, and performance:

- **Design:** The construction of the subject devices and predicate are similar by providing a visual image of the surgical site. The subject devices and predicate device interface with an external monitor. The predicate and subject devices make use of a control box to allow for light output and white balance adjustment. The predicate device transmits an analog image through the endoscope using fiber optics. The subject devices incorporate a CMOS digital imaging sensor at the distal tip of the endoscope. The digital signal is transmitted through the

endoscope to the Digital Control Module. The predicate device includes capability to store patient images and data whereas the subject devices do not store patient information. The predicate device endoscope portion of the system allows for reuse, whereas the subject device endoscopes are single use only.

- **Materials:** The materials of the subject devices, predicate, and references are very similar medical grade stainless steel and or plastics.
- **Environment of Use:** The use environments are the same as the predicate and reference devices. The control modules are located outside of the sterile field and are non-sterile reusable components and power supply accessories. The subject devices, predicate, and reference device are used in healthcare facilities by qualified healthcare professionals.

Differences in Indications for Use:
The Indications for Use are similar, however will only include orthopedic related indications for use.

H. Non-Clinical Performance Data:
The Digital ClarusScope, Digital NeuroPEN, and Digital Control Module have been thoroughly tested through verification of product specifications and user requirements. The following quality assurance and performance measures were applied during the development of the systems:

- Performance Testing (Verification):
  - Endoscope dimensional verification
  - Mechanical strength requirements
- Functional Tests
  - Endoscope fluid patency
  - System image output
- Simulated Use Test
  - Interconnection testing between endoscope and control module and accessories
  - Compatibility with introducer
  - Compatibility of endoscope working channel with accessory devices

I. Substantial Equivalence Conclusion:
Clarus Medical has demonstrated through design and non-clinical testing that the proposed subject devices are substantially equivalent to the predicate device.
The subject devices and the reference device are identical in construction materials, manufacturing processes, firmware, sterilization cycle, and packaging. The only difference between the subject devices and reference device is the indications for use.