April 25, 2024

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

Re: K240535
Trade/Device Name: Digital ClarusScope System; Digital NeuroPEN System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: February 23, 2024
Received: February 26, 2024

Dear Alan 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 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.

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,

Ryan Trombetta -S Digitally signed by Ryan Trombetta -S
Date: 2024.04.25 11:43:56 -04'00'

For: 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

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)*
K240535

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 spinal nerve roots, foramina, intervertebral disc, and surrounding tissues of the spine during discectomy procedures, bone and osteophyte removal, and procedures associated with ruptured or herniated discs.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

A. General Information:

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

Establishment Number: 2183911

Contact: Mark F. Brown
Director of Operations
mbrown@clarus-medical.com

Date Prepared: April 23, 2024

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
K974579	Clarus Model 2600 Neuro Endoscope

D. Reference Devices:

510(k) Number	Description
K223615	Clarus Digital ClarusScope System and Digital NeuroPEN System

E. Device Description:

System level description;

The Digital ClarusScope System and Digital NeuroPEN System are spinal endoscopes which provide 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 spinal 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.

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, spinal endoscope 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 spinal nerve roots, foramina, intervertebral disc, and surrounding tissues of the spine during discectomy procedures, bone and osteophyte removal, and procedures associated with ruptured or herniated discs.

G. Comparison to Predicate and reference Devices:

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

Differences in Indications for Use:

The Indications for Use is similar to the predicate device. The endoscopes are used for visualization, diagnostic and/or therapeutic procedures of structures within the spine during surgical procedures.

K240535

510(K) Summary

Substantial Equivalence table

	Subject Device	Predicate Device	Reference Device
Device Name	Clarus Digital ClarusScope System, and Digital NeuroPEN System	Clarus Model 2600 Neuro Endoscope	Clarus Digital ClarusScope System and Digital NeuroPEN System
510(k)	TBD	K974579	K223615
Product code	HRX	HRX	GWG
Indication for use	The Digital ClarusScope System and Digital NeuroPEN System are intended for accessing and visualizing the spinal nerve roots, foramina, intervertebral disc, and surrounding tissues of the spine during discectomy procedures, bone and osteophyte removal, and procedures associated with ruptured or herniated discs.	The Model 2600 Endoscope is intended for accessing and visualizing the spinal nerve roots, foramina, intervertebral disc, and surrounding tissues of the lumbar spine. The endoscope has a working channel intended for the passage of surgical instruments indicated for use in this area. Surgical instrumentation may be used for discectomy procedures, bone and osteophyte removal, procedures associated with ruptured or herniated discs, such as retrieval of extruded disc fragments and retrieval of free fragments. The endoscope also has an irrigation channel for irrigation flush or aspiration.	The Digital ClarusScope System and Digital NeuroPEN System are intended for use in neurosurgery, endoscopic neurosurgery, and ventriculoscopy for visualization of ventricles and structures within the brain during neurological surgical procedures, diagnostic and/or therapeutic procedures such as ventriculostomies, biopsies and removal of cysts, tumors and other obstructions.
Type of scope	Digital ClarusScope; Rigid Digital NeuroPEN: passively deflective	Rigid	Digital ClarusScope; Rigid Digital NeuroPEN: passively deflective
Insertion shaft diameter	1 to 4.2mm	4.2 to 5.2 mm	1 to 4.2mm
Insertion Shaft Length	13cm Digital ClarusScope 15.5cm Digital NeuroPEN	18.8cm	13cm Digital ClarusScope 15.5cm Digital NeuroPEN
Light source	External LED (intensity adjustable)	Same	External LED (intensity adjustable)

	Subject Device	Predicate Device	Reference Device
Image acquisition	Distal tip CMOS, color, video, camera	Lens and imaging fiberoptics at distal tip	Distal tip CMOS, color, video, camera
Image processing	Image is digitally processed by control unit with embedded firmware	None	Image is digitally processed by control unit with embedded firmware
Image display	External display monitor connection	External display with camera system or viewed through eyepiece	External display monitor connection
Sterile	EO	Provided non sterile; EO compatible	EO
Use	Single Use	Reusable	Single Use
Image control Box	Electronics (Circuit boards, CPU with firmware control), Keypad buttons for illumination adjustment by user	None	Electronics (Circuit boards, CPU with firmware control), Keypad buttons for illumination adjustment by user

510(K) Summary

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:

- Requirements/Specification Reviews
- Design Reviews
- 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

Sterility

- ETO Sterilization Validated per ISO 11135-1
- Shelf-Life per ASTM F1980
- Distribution per ASTM D4169

Biocompatibility per ISO 10993-1

- Cytotoxicity (MEM Elution)
- -Sensitization (Kligman Maximization)
- -Irritation (Intracutaneous Injection)
- -Systemic Toxicity (Systemic Injection)
- -Hemolysis (In direct)
- -Materials Mediated Pyrogenicity

Electrical Safety and Electromagnetic Compatibility

- Particular Safety of Endoscopic Equipment per IEC 60601-2-18
- Basic safety and Essential Performance per IEC 60601-1
- Electromagnetic Immunity and Emissions per IEC 60601-1-2

I. Comparison to Predicate and reference devices:

The Digital ClarusScope System and Digital NeuroPEN System are substantially equivalent to the predicate based on the following technological elements:

- **Design:** The construction of the subject device and predicate are similar by providing a visual image of the surgical site. 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 and subject devices all makes use of a control box to allow for light output and white balance adjustment.

- **Materials:** The materials of the subject devices, predicate, and references are very similar medical grade stainless steel and or plastics.
- **Environment of Use:** The subject device, predicate, and reference device are used in healthcare facilities by qualified healthcare professionals.

The following technological differences exist between the subject and predicate devices:

The construction of the subject device and the predicate are the same with the addition of a distal tip camera in the subject device. The subject device also makes use of a control box to allow for light output and white balance adjustment.

Substantial Equivalence Conclusion:

Clarus Medical has demonstrated through performance testing, design and non-clinical testing that the proposed subject device and the predicate device have been found to be substantially equivalent.