



November 21, 2023

Clarus Medical, LLC
Mark Brown
Director of Operations
13355 10th Avenue N Suite 110
Plymouth, Minnesota 55441

Re: K223615
Trade/Device Name: Digital ClarusScope System
Digital NeuroPEN System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: October 20, 2023
Received: October 23, 2023

Dear Mark Brown:

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,

Adam D. Pierce -S Digitally signed by
Adam D. Pierce -S
Date: 2023.11.21
08:46:56 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional

and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K223615

Device Name

Digital ClarusScope System

Digital NeuroPEN System

Indications for Use (Describe)

The Digital ClarusScope System and Digital NeuroPEN System are intended for use in neurosurgery, endoscopic neurosurgery, and ventriculoscopia 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 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**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: November 16, 2023

B. Trade Name:

Digital ClarusScope System
 Digital NeuroPEN System
 Endoscope, Neurological
 GWG
 21 CFR 882.1480
 Neurological endoscope
 II

Common Name:
 Product Code:
 Regulation Number:
 Regulation Name:
 Class:

C. Predicate Device:

510(k) Number
 K945633

Description
 Clarus Model 2232 Neuro Channel Scope

D. Reference Devices:

510(k) Number
 K942249
 K161112

Description
 Clarus NeuroPEN Endoscopes
 KARL STORZ Flexible Video-Neuro-Endoscope System

E. Device Description:

System level description;

The Digital ClarusScope System and Digital NeuroPEN System are neurological 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 neurological 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

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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 ClarusScope Model number: 2100-500

Description: The Digital ClarusScope is a sterile, single use, neurological 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 NeuroPEN Model number: 2120-515

Description: The Digital NeuroPEN is a sterile, single use, neurological endoscope with a distal tip camera, light source, and irrigation channel. The 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 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 use in neurosurgery, endoscopic neurosurgery, and ventriculostomy 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.

G. Comparison to Predicate and reference Devices:

The Digital ClarusScope System and Digital NeuroPEN System are substantially equivalent to the predicate devices in terms of design, materials, and performance. The

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predicate and subject devices have similar indications and very similar construction.

Differences in Indications for Use:

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

Comparison of technological characteristics:

	Subject Device	Predicate Device	Reference Device	Reference Device
Device Name	Digital ClarusScope System and Digital NeuroPEN System	Clarus Model 2232 Neuro Channel Scope	Clarus NeuroPEN Endoscopes	KARL STORZ Flexible Video-Neuro-Endoscope System
<u>510(k)</u>	<u>K223615</u>	K945633	K942249	K161112
Product code	GWG	GWG	GWG	GWG
Indication for use	The Digital ClarusScope System and Digital NeuroPEN System are intended for use in neurosurgery, endoscopic neurosurgery, and ventriculostomy 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.	The Model 2232 is intended as both a diagnostic instrument to visualize the intracranial space and the surrounding tissues of the brain, and to allow the passage of surgical instruments.	The Clarus NeuroPEN and Channel Scope endoscopes is intended for accessing and visualizing nerves, neural tissue and surrounding tissue where cerebrospinal fluid (CSF) may be contacted during neurosurgical (including intracranial) procedures. The endoscope is passively deflectable and has an irrigation channel for sterile fluid flush.	The KARL STORZ Flexible Video-Neuro-Endoscope System is indicated to provide visualization and access during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection, hydrocephalus treatment, endoscopic third ventriculostomy with choroid plexus cauterization (ETV/CPC), endoscopic third ventriculostomy, cyst fenestration, and aqueduct exploration.
Type of scope	Digital ClarusScope: Rigid Digital NeuroPEN: passively deflective	rigid	passively deflective	flexible

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Insertion shaft diameter	4.2mm Digital ClarusScope 1.14mm Digital NeuroPEN	3.5 to 4.2 mm	1.14mm	3.2mm x 2.4mm
Insertion Shaft Length	13cm Digital ClarusScope 15.5cm Digital NeuroPEN	13.0cm and 21.6cm	15.5cm and 19.0cm (NeuroPEN)	35 cm
Light source	External LED (intensity adjustable)	same	External Xenon bulb (intensity adjustable)	External light source
Image acquisition	Distal tip CMOS, color, video, camera	Lens and imaging fiberoptics at distal tip	Lens and imaging fiberoptics at distal tip	Distal tip CMOS, color, video, camera
Image processing	Image is digitally processed by control unit with software	none	none	Image is digitally processed by control unit with software
Image display	External display monitor connection	External display with camera system or viewed through eyepiece	External display with camera system or viewed through eyepiece	External display monitor connection
Sterile	EO	same	same	same
Use	Single Use	same	same	same
Image control Box	Electronics (Circuit boards, CPU with firmware control), Keypad buttons for illumination adjustment by user	none	none	same

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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
- Environmental Conditioning per ASTM D4332
- 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, predicate, and the reference devices are similar with the addition of a distal tip imaging device in the subject device. The subject device also makes use of a control box to allow for light output and white balance adjustment.
The Karl Storz reference device uses the same CMOS distal tip imaging technology with digital control box as the subject device.
- **Materials:** The materials of the subject device, predicate, and references are very similar medical grade stainless steel and or plastics.
- **Environment of Use:** The subject device, predicate, and reference devices must be used by a physician in a healthcare facility.
- **Patient Population:** The patient populations are the same as the predicate and reference devices, namely, adult patients.

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.