March 18, 2021

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

Re: K200925
Trade/Device Name: Peel-Away Introducer Sheath
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: February 11, 2021
Received: February 16, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200925

Device Name
Clarus Peel-Away Introducer Sheath

Indications for Use *(Describe)*

The Clarus Peel-Away Introducer Sheath is intended to be used in indications requiring access through the brain into the ventricular system.

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:

510(K) Submission Number:	K200925
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 3, 2020

B. Trade Name:	Clarus Peel-Away Introducer Sheath
Common Name:	Endoscope Introducer
Product Code:	GWG
C.F.R Section:	882.1480
Class:	II

C. Predicate Device:

510(k) Number	Description
K990333	Medtronic Peelaway Introducer Sheath

D. Reference Devices:

510(k) Number	Description
K883607	Codman® Peel-Away Catheter Introducer
K120617	Martech Medical Products Super Sheath Introducer

E. Device Description:

The Clarus Peel-Away Introducer Sheath is a thin-walled, cylindrical device that is placed in position so that it provides a communicating passageway through brain tissue. This is accomplished by fitting the sheath securely over an obturator, advancing both devices through the tissue together as a unit. A hole through the distal tip of the obturator aids in placement by allowing pressurized cerebrospinal fluid to egress once the ventricular system is reached. The proximal hub on the obturator is rotated, unlocking it from the sheath, and the obturator is removed from the sheath, leaving the sheath alone in the desired position acting to hold the penetrated site in an open condition. The peel away sheath is capable of being pulled apart lengthwise to allow varying insertion depths into brain tissue. The proximal end of the sheath has tab handles that are provided to facilitate grasping and tearing. At this point, a regulatorily cleared device can be inserted through the sheath for patient procedures.

The Peel-Away Introducer Sheath has the following parts:

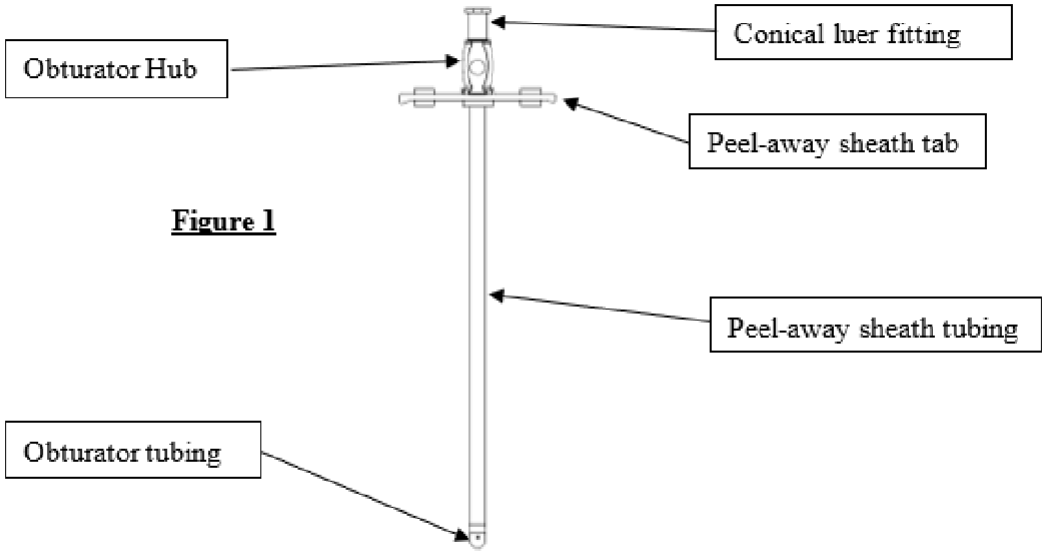


Figure 1

Figure 2

Component description:

Obturator hub: The obturator hub is injection molded directly onto the obturator tubing with high-density polyethylene (HDPE) resin. The hubs are color coded to indicate the French size. Also, the French size number is molded onto the side of the hub

Obturator tubing: The tubing for the obturator is extruded using high-density polyethylene (HDPE) resin with 15% barium sulfate to aid in visualization under fluoroscopy.

Peel-away Sheath tabs: The peel-away sheath tabs are injection molded directly onto the sheath tubing with high-density polyethylene (HDPE) resin. The molded tabs incorporate a slot to allow the obturator hub to lock onto the sheath.

Peel-away sheath: The sheath tubing is extruded using Polytetrafluoroethylene PTFE resin with 9% Bismuth oxide to aid in visualization under fluoroscopy.

F. Intended Use:

The Clarus Peel-Away Introducer Sheath is intended to be used in indications requiring access through the brain into the ventricular system.

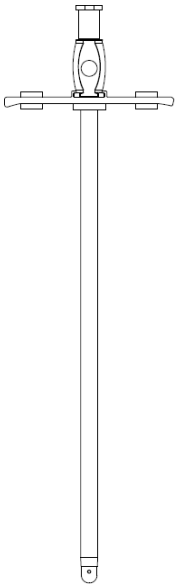
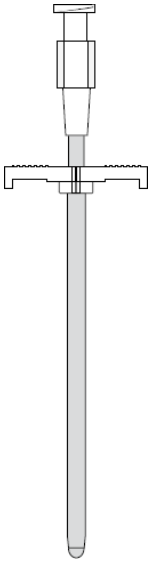
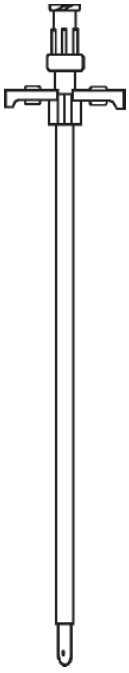
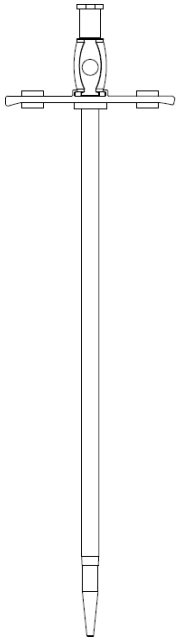
G. Comparison to Predicate and reference Devices:

The Clarus Peel-Away Introducer Sheath is substantially equivalent to the predicate and reference devices based on the following technological elements:

- Design: The predicate and reference devices all have a two-part design, a peel-away sheath and an inner obturator introducer. Both parts lock together.
- Materials: The materials of the subject device and the Medtronic predicate device are very similar, and the Martech Medical Products PTFE Super Sheath reference device are identical in terms of materials.
- Construction: The construction of the subject device and predicate Medtronic Peelaway Introducer Sheath are very similar. They both include two parts, a peel-away sheath and a blunt distal tip obturator, which fits inside the sheath.
- Environment of Use: The Clarus Peel-Away Introducer Sheath and the Medtronic Peelaway Introducer Sheath must be used by a physician in a healthcare facility.

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

- The way in which the outer sheath and obturator lock together is different. The subject device locks to the sheath by rotating the obturator a quarter turn engaging two side tabs into the sheath. The predicate device snaps together.
- The way in which fluid can be drained is different. The subject device has a small hole at the distal tip of the obturator to aid in placement by allowing pressurized cerebrospinal fluid to egress once the ventricular system is reached. The predicate device does not have this feature which requires the user to completely remove the obturator to relieve pressurized fluid. The Codman reference device obturator distal tip designs are identical. They both have a hole through the side to aids in placement by allowing pressurized cerebrospinal fluid to egress once the ventricular system is reached.

	Subject Device	Predicate Devices	Reference Device	Reference Device
Trade Name	Clarus Peel-Away Introducer Sheath	Medtronic Peelaway Introducer Sheath	Codman® Peel-Away Catheter Introducer	Martech Medical Products PTFE Super Sheath Introducer
510(k)	K200925	K990333	K883607	K120617
Indications for Use	The Clarus Peel-Away Introducer Sheath is a device used to make a channel through the brain into the ventricular system.	The Introducer Sheath is a device used to make a channel through the brain into the ventricular system.	The Peel-Away Catheter Introducer assists in placing a catheter in the ventricle when hydrocephalus shunting is indicated and when using an endoscope.	The PTFE Super Sheath Introducers are intended to obtain central venous access to facilitate catheter insertion or placing pacing leads into the central venous system.
Image				
Product Code	GWG	GWG	GYK	DYB
Enviornment of use	Rx Only	Rx Only	Rx Only	Rx Only
Sheath Diameter and Length	12F, 14F, 15F 8-13cm	12F, 14F, 15F 9.5cm	9F, 11F, 12.5F, 14F 14.7cm	5F through 18F 10cm and 13.5cm
Sterilization method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Conditions supplied	Sterile, single use	Sterile, single use	Sterile, single use	Sterile, single use
Device components	Peel-away Sheath, obturator	Peel-away Sheath, obturator	Peel-away Sheath, obturator	Peel-away Sheath, dilator

H. Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Clarus Peel-Away Introducer Sheath was conducted with the following FDA guidance, “Use of International Standards ISO 10993-1,"Biological evaluation of medical devices - Part 1: Evaluation and testing within risk management process”. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemocompatibility
- Material-Mediated Endotoxin

The nature of body contact and the related device category:
Category: External Communicating device
Contact: Circulating Blood
Contact Duration: limited (<24 hours)

The selected tests are appropriate based on the intended use for the Clarus Peel-Away Introducer Sheath. All tests results are acceptable demonstrating the Clarus Peel-Away Introducer Sheath is safe for its intended use.

Mechanical Testing:

Components of the Clarus Peel-Away Introducer Sheath and predicate devices were tested for:

Test performed	**Description**	**Test results**
Fluid Patency	Visually inspect inside diameter for cleanliness and quality of manufacturing.	Pass. All devices had comparable results.
Prolapse Force	Resistance to deformation of device while advancing distal end into flat plate. Force was measured.	Pass. All devices had comparable results.
Peek Tensile Force	Measure peak tensile force of inner obturator/dilator and sheath hub per ISO 11070.	Pass. All devices had comparable results.
Peel Force	Each sheath is gripped and force measure to break hub, and peel sheath.	Pass. All devices had comparable results.

The subject device and predicate devices were found to be substantially equivalent in performance.

Clinical and animal Studies:

No animal studies were required (other than biocompatibility testing) for the Clarus Peel-Away Introducer Sheath.

No clinical studies were required for the Clarus Peel-Away Introducer Sheath to support substantial equivalence.

I. Conclusion

The non-clinical data supports the safety of the device and performance verification & validation testing demonstrate that the Clarus Peel-Away Introducer Sheath should perform as intended in the specified use conditions. Testing demonstrates that the Clarus Peel-Away Introducer Sheath is substantially equivalent to the predicate device.