April 2, 2021

ClearMind Biomedical
℅ Craig Coombs
President
Coombs Medical Device Consulting, Inc.
1100 Pacific Marina, Suite 806
Alameda, California 94501

Re: K210251
Trade/Device Name: ClearPath Disposable Introducer
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: January 28, 2021
Received: January 29, 2021

Dear Craig Coombs:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210251

Device Name
ClearPath Disposable Introducer

Indications for Use *(Describe)*
The ClearPath Disposable Introducer is indicated to obtain and maintain a temporary pathway into the ventricular system and cerebrum of the brain.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

ClearPath™ Disposable Introducer
510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	ClearMind Biomedical 5F, No. 167, Fuxing N. Rd., Songshan Dist., Taipei City 105, Taiwan, R.O.C. +886-2-22697417
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting, Inc 1100 Pacific Marina, Suite 806 Alameda, CA 94501 Tel: 510-995-8499
Device Common Name:	Neurological Endoscope Introducer
Device Regulation & Name:	21 CFR 882.1480 Neurological Endoscope
Classification & Product Code: 510(k) Number:	Class II, GWG K210251
Device Proprietary Name:	ClearPath™ Disposable Introducer

Predicate Device Information:

Predicate Device:	MINOP Disposable Introducer 26F
Predicate Device Manufacturer:	Aesculap Inc.
Predicate Device Common Name:	Endoscope, Neurological
Predicate Device Premarket Notification #	K142315
Predicate Device Classification & Name	21 CFR 882.1480
Predicate Device Classification & Product Code:	Class II GWG

B. Date Summary Prepared

30 March 2021

C. Description of Device

The ClearPath™ Disposable Introducer is a sterile, single-use, neurological endoscope Introducer, consisting of a Sheath and a Dilator.

A locking mechanism design allows the Dilator to lock into the Sheath and prevent "push back" during insertion into the brain. The Dilator tip is designed to be atraumatic during insertion. The Sheath is graduated in centimeters to assist the surgeon in determining the Introducer insertion depth. The Sheath's transparency is useful for full endoscopic visualization during insertion.
The proximal end of the Sheath is labeled 20F, indicating the inner diameter of the Sheath.

D. Indications for Use

The ClearPath Disposable Introducer is indicated to obtain and maintain a temporary pathway into the ventricular system and cerebrum of the brain.

E. Tabular Comparison of Application and Predicate Devices in Regard to Substantial Equivalence

Characteristic	Application Device: ClearMind Biomedical ClearPath™ Disposable Introducer	Predicate Device: MINOP® Disposable Introducer 26F K142315	Impact on Substantial Equivalence
Company	ClearMind Biomedical	Aesculap	-
Regulation Number	21 CFR 882.1480	21 CFR 882.1480	Identical
Product Code	GWG	GWG	Identical
Indications for Use	The ClearPath™ Disposable Introducer is indicated to obtain and maintain a temporary pathway into the ventricular system and cerebrum of the brain.	The MINOP® Disposable Introducer is indicated to obtain and maintain a temporary pathway into the ventricular system of the brain. The purpose of the Minop ® Disposable Introducer is to obtain and maintain a temporary pathway to the ventricular system of the patient. The Minop® Disposable Introducer is designed to be split lengthwise and peeled down to the skull level of the patient, accommodating different depth requirements.	The Indications for Use are clinically identical. Both devices are intended to provide a temporary pathway into the brain, down to the level of the ventricular system. The access to the ventricular system occurs only after passing through the cerebrum. The application device adds detail that is implicit in the predicate Indications for Use. The application Indication for Use does not repeat the Indications for Use like the predicate does in its second sentence. The application device drops the predicate's design description as unnecessary in an Indications for Use. The differences between the Indications for Use raise no new questions of safety or efficacy.
Technology	An insert (dilator) is temporarily fixed within a tube (sheath) that can be atraumatically advanced to the target site. The insert is removed and the tube can be split to either side to facilitate the placement of a neuro endoscope.	An insert (obturator) is temporarily fixed within a tube (sheath) that can be atraumatically advanced to the target site. The insert is removed and the tube can be split to either side to facilitate the placement of a neuro endoscope.	Technology is identical.

Characteristic	Application Device: ClearMind Biomedical ClearPath™ Disposable Introducer	Predicate Device: MINOP® Disposable Introducer 26F K142315	Impact on Substantial Equivalence
Design	ClearPath™ Disposable Introducer consists of two main components: sheath and dilator. The sheath is a hollow tube and the dilator is a solid rod that fills the hollow tube as it is advanced through the brain to the target area. After the sheath is confirmed to have been advanced to the target area, it can be peeled in half, down to the level of the skull, to facilitate the advancement of the neuroendoscope. Interlocking hub design that prevents dilator "push back" during insertion. Printed graduation on the sheath to assist the surgeon in determining the depth the introducer has been inserted and prevent advance deeper than desired. Transparent sheath for observing surrounding tissue and brain through an endoscope	The MINOP Disposable Introducer 26F consists of two main components: sheath and obturator. The sheath is a hollow tube and the obturator is a solid rod that fills the hollow tube as it is advanced through the brain to the target area. After the sheath is confirmed to have been advanced to the target area, it can be peeled in half, down to the level of the skull, to facilitate the advancement of the neuroendoscope. Interlocking hub design that prevents obturator "push back" during insertion. Printed graduation on the sheath to assist the surgeon in determining the depth the introducer has been inserted and prevent advance deeper than desired Opaque Sheath.	Similar. The transparent sheath of application device does not raise new risk of safety.
Inner Diameter of Sheath	20 Fr (6.68 mm)	26 Fr (8.67 mm)	The application device is smaller than predicate device by only 2 mm in ID and OD. The 20Fr size is similar to other neuro introducers like the MINOP Introducer (K061135) which ranges in cleared size

Characteristic	Application Device: ClearMind Biomedical ClearPath™ Disposable Introducer	Predicate Device: MINOP® Disposable Introducer 26F K142315	Impact on Substantial Equivalence
			from 10 – 19Fr. The MINOP Introducer was the predicate for this submission's predicate device.
Outer Diameter of Sheath	7.4 mm	9.33 mm	Same justification as in the cell above.
Max Useable Sheath Length	120 mm	120 mm	Identical
Dilator OD	6.6 mm	8.5 mm	Outer diameter of the application device is smaller than predicate. Each dilator compatible with its sheath and raises no new questions of safety or efficacy.
Materials	Polymers & Colorant	Not described Some polymers	The material of the application device has been widely used in similar applications in medical devices. The application device has passed appropriate biocompatibility testing.
Graduations	Graduation 1 to 12 on sheath and in centimeter per grid	Graduation 1 to 12 on sheath and in centimeter per grid	Identical
Radiopacity	Non-radiopaque	Non-radiopaque	Identical
Principal Operator	Surgeon	Surgeon	Identical
Use Location	Operating room	Operating room	Identical

F. Summary of Supporting Data

Biocompatibility data demonstrates that the device is in compliance with ISO 10993.

Bench testing has demonstrated that the ClearPath™ Disposable Introducer is in compliance with its specifications and its labeling claims.

Transit testing demonstrates that the device is in compliance with ASTM D4169.

Shelf life studies demonstrate that the ClearPath™ Disposable Introducer could be stored in a sterile manner for 2 years.

G. Conclusion

Based on intended use, performance and supporting documentation, ClearMind Biomedical concludes that the ClearPath™ Disposable Introducer is substantially equivalent in intended use, indications for use, technology, principal operator, use location, sterilization method and contact duration of the predicate MINOP® Disposable Introducer 26F device (K142315).