April 26, 2024

ClearPoint Neuro Inc.
Brennan Sullivan
Regulatory Affairs Manager
120 S. Sierra Avenue, Suite 100
Solana Beach, California 92075

Re: K233703
Trade/Device Name: Bone Anchor (NGS-BA-01)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: March 27, 2024
Received: March 27, 2024

Dear Brennan Sullivan:

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: 2024.04.26 08:11:29 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233703

Device Name

Bone Anchor (NGS-BA-01)

Indications for Use *(Describe)*

The Bone Anchor is intended to be used with commercially available stereotactic systems for intracranial and neurosurgical procedures which require accurate positioning of compatible small surgical instruments or accessories in the cranium, brain, or nervous systems. It is designed to provide short-term fixation and positioning of compatible neurosurgical instruments or accessories under image-guidance.

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

510(k) Summary
for the ClearPoint Neuro
Bone Anchor
(per 21CFR 807.87)

3. SUBMITTER/510(K) HOLDER

ClearPoint Neuro, Inc.
120 S. Sierra Ave.
Suite 100
Solana Beach, CA 92075
Contact Person: Brennan Sullivan
Telephone: 617-678-1028

Date Prepared: March 26, 2024

2. DEVICE INFORMATION

Name of Device:	Bone Anchor
Common or Usual Name:	Stereotaxic Instrument
Classification:	Stereotaxic Instrument
Regulatory Class:	Class II
Product Code	HAW (21 CFR 882.4560)

3. PREDICATE DEVICES

Primary Predicate

FHC Microtable System	K132611

Reference Device

SmartFlow Flex Ventricular Catheter	(bone anchor component)	K123605

4. DEVICE DESCRIPTION

The Bone Anchor is a single-use device for temporary short-term fixation of surgical tools or accessories during a single surgical procedure. The Bone Anchor may be used during image-guided or MR interventional procedures. This device is not intended to create a seal or barrier from potential infection and has not been tested for long-term (>24 hours) use.

The Bone Anchor components are listed below along with their function:

- Bone Anchor (Skull Device) – A device that is inserted into the Skull that is used to hold an instrument or accessory in place after is it inserted to the desired position. Part of the Skull Fixation Device protrudes from the Skull.
- Bone Anchor Driver (Driver) – An optional device used to position the Skull Fixation Device into the skull.
- Bone Anchor Silicone Seal – A device within the Bone Anchor which is compressed against the inserted instrument or accessory when the Cap is tightened, thereby holding the instrument or accessory in place.
- Bone Anchor Cap – A device which connects to the Bone Anchor and, when tightened, compresses the Silicone Seal against the inserted instrument or accessory.
- Bone Anchor Cover – An optional device which is placed over the Cap when inserting a flexible instrument or other accessory and can be locked into place on the Cap to secure the accessory.

5. INDICATIONS FOR USE

The Bone Anchor is intended to be used with commercially available stereotactic systems for intracranial and neurosurgical procedures which require accurate positioning of compatible small surgical instruments or accessories in the cranium, brain, or nervous systems. It is designed to provide short-term fixation and positioning of compatible neurosurgical instruments or accessories under image-guidance.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Bone Anchor is equivalent in indications and intended use to FHC Microtable System, subject of K132611. The Bone Anchor is also similar in its operational characteristics to the Microtable in that they are used with commercially available Stereotactic Navigation Systems (SNS) to provide fixation and alignment for surgical instruments. Both devices are fixed to the patient's skull and allow for surgical instruments to be pass through the device and into the patient before the instrument can be fixed in place once it reaches the desired target. The devices differ in that the Microtable is a custom device that is manufactured specifically for each patient while the Bone Anchor is a standard device that is not custom-made. Additionally, the Bone Anchor is screwed directly into the patient's skull while the Microtable is affixed to the patient using 3 or more bone screws. These differences do not impact the safety or efficacy of the Bone Anchor when compared to the predicate device.

ClearPoint has manufactured the Bone Anchor as part of another device family, the SmartFlow Flex Ventricular Catheter cleared under K123605 and distributed by Brainlab as Brainlab Flexible Catheter (Model Numbers: 19770, 19771, 19772 and 19773). Therefore, the proposed Bone Anchor is identical to the Bone Anchor that was cleared by the Food and Drug Administration as part of the SmartFlow Flex Ventricular Catheter 510(k) submission, subject of K123605. This device was cleared with a different indication for use from the proposed Bone Anchor. The indications for use are different because the bone anchor is a component of a delivery device; however, the use and functionality are

identical to that of the proposed Bone Anchor and the Visualase Bone Anchor in that they all provide fixation to the skull and provide both fixation and trajectory for small surgical instruments or accessories, during neurosurgical procedures.

The Bone Anchor is the identical device to the Bone Anchor component of the ClearPoint SmartFlow Flex Ventricular Catheter subject of K123605. The design, materials of manufacture, and dimensions are identical since ClearPoint manufactures this component on behalf of Brainlab (the distributor of the SmartFlow Flex). The proposed Bone Anchor and the predicate Bone Anchor subject of K123605 include the bone anchor, seal, cap, cover, and driver components.

7. CONCLUSION

The ClearPoint Neuro Bone Anchor is substantially equivalent to the primary predicate, MicroTable and reference Bone Anchor component of the SmartFlow Flex Ventricular Catheter devices. The Bone Anchor is the identical device to that which ClearPoint manufactures and supplies as a component to the SmartFlow Flex Ventricular Catheter cleared under K123605 (currently distributed by Brainlab). The Bone Anchor is substantially equivalent to the MicroTable because the subject device raises no new issues of safety and effectiveness, meets all test specifications, and the non-clinical testing performed demonstrates that the subject device is as safe, as effective, and performs as well as the predicate device. Additionally, The Bone Anchor is identical in design and operational and technological characteristics to the SmartFlow Flex Ventricular Catheter Bone Anchor.

The proposed Bone Anchor is identical to the reference Bone Anchor that was part of K123605. In addition, the clinical utility and functionality are similar to the primary predicate Microtable System subject of K132611, and do not raise any new concerns of safety or efficacy. A side-by-side comparison of the subject device to the predicate can be found below in Table 1

Table 1: Side-by-Side Comparison of ClearPoint Bone Anchor to Predicates

Characteristic	Subject Device Proposed ClearPoint Neuro Bone Anchor	Primary Predicate FHC Microtable Stereotactic System K132611	Reference Device ClearPoint Neuro (manufactured for Brainlab) Bone Anchor Component SmartFlow Flex Ventricular Catheter K123605	Discussion
Classification	Stereotaxic Instrument 21 CFR 882.4560	Stereotaxic Instrument 21 CFR 882.4560	Ventricular Catheter 21 CFR 882.4100	Identical
Product Code	HAW	HAW	HCA	Identical
Intended use	The Bone Anchor is intended to provide fixation to the skull and provide both fixation and trajectory for small surgical instruments or accessories, during neurosurgical procedures..	The Microtable System is a patient-specific surgical adapter, designed to be secured on a skull-based anchor mounting set to hold and align surgical instruments with patient anatomy and to allow selected targets to be reached with sub-millimeter accuracy.	The SmartFlow Flex Ventricular Catheter is intended for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. The device is not intended for implant. This device is intended for single patient use only.	Similar
Indications for Use	The Bone Anchor is intended to be used with commercially available stereotactic systems for intracranial and neurosurgical procedures which require accurate positioning of compatible small surgical instruments or accessories in the cranium, brain, or nervous systems. It is designed to provide short-term fixation and positioning of compatible neurosurgical instruments or accessories under image-guidance.	The Microtable Stereotactic System is intended to be used with commercially available stereotactic systems for intra-cranial and neurosurgical procedures which require the accurate positioning or microelectrodes, stimulating electrodes, or other instruments in the cranium, brain, or nervous systems .	The SmartFlow Flex Ventricular Catheter is intended for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. The bone anchor component provides fixation to the skull for fixation and trajectory of instruments or accessories during neurosurgical procedures.	Similar to primary predicate Functionality identical to reference predicate
Principles of Operation	• A 3.2-3.4 mm access hole is drilled into the patient's skull.	• Microtable is custom-made for the patient	• A 3.2-3.4 mm access hole is drilled into the patient's skull.	Essentially identical

	• The Bone Anchor is mounted into the access hole manually or using the Driver to keep the bone anchor aligned to the trajectory guidance equipment. • An instrument or accessory is inserted through the Bone Anchor. • The Cap is hand tightened to secure the device.	• Microtable is affixed to patient's skull using bone-mounted anchors • Instrument or accessory is inserted through the Microtable • Device can be secured using	• The Bone Anchor is mounted into the access hole manually or using the Driver. • The Bone Anchor is screwed into the skull until it is tight. • An instrument or accessory is inserted through the Bone Anchor. • The Cap is hand tightened to secure the device.	
Where used	MRI Suite/ Surgical Room (OR)	MRI Suite/ Surgical Room (OR)	MRI Suite/ Surgical Room (OR)	Identical
Anatomical Sites	Skull	Skull	Skull	Identical
Design	A bone anchor device that is inserted into the Skull that is used to hold an instrument or accessory in place after it is inserted to the desired position. Components include a bone anchor, driver, silicone seal, cap and cover.	Microtable System is composed of the following: • Custom-made Microtable • Mounting hardware and tools	This kit includes a ventricular catheter and bone anchor device that is inserted into the Skull to hold an instrument or accessory in place after is it inserted to the desired position. Components include a bone anchor driver, silicone seal, cap and cover.	Identical to primary predicate Functionality identical to reference predicate
Working Lumen Size	1.8-2.1 mm	N/A, Device is patient-specific	1.8-2.1 mm	Similar
Drill Size	3.2-3.4 mm	N/A, Device is patient-specific	3.2-3.4 mm	Similar
Materials	• Nylon • Silicone • PEEK	Polycarbonate or Ultem	• Nylon • Silicone • PEEK	Similar to primary predicate. Identical to reference predicate.
Performance Testing	• Load Testing • Push Force Testing	• Dimensional Stability • Load Testing	• Load Testing • Push Force Testing	Identical to Reference

	• Insertion Force Testing • Retention Force Testing • Removal Force Testing • Driver Pull Force Testing	• Targeting Error	• Insertion Force Testing • Retention Force Testing • Removal Force Testing • Driver Pull Force Testing	Predicate, similar to Primary Predicate