January 12, 2024

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

Re: K233144
Trade/Device Name: ClearPoint Bone Screw Fiducials
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: December 8, 2023
Received: December 11, 2023

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: 2024.01.12 16:44:57 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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)*
K233144

Device Name
ClearPoint Bone Screw Fiducials

Indications for Use *(Describe)*
The ClearPoint Bone Screw Fiducials are intended to provide fixed reference point(s) in patients requiring stereotactic surgery in conjunction with CT imaging.

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
ClearPoint Bone Screw Fiducials
(per 21CFR 807.87)

1. SUBMITTER/510(K) HOLDER

ClearPoint Neuro, Inc.
120 S. Sierra Ave.
Suite 100
Solana Beach, CA 29075
Contact Person: Brennan Sullivan
Telephone: 617-678-1028

Date Prepared: January 11, 2024

2. DEVICE INFORMATION

Name of Device:	ClearPoint Bone Screw Fiducials
Common or Usual Name:	Bone Screw Fiducials
Classification:	Neurological Stereotaxic Instrument, 21CFR 882.4560
Regulatory Class:	Class II
Product Code	HAW

3. PREDICATE DEVICE

- Medtronic Unibody Bone Fiducials K033619

4. DEVICE DESCRIPTION

The ClearPoint Bone Screw Fiducials are titanium bone screw fiducials that provide fixed reference points during neurosurgical procedures.

The ClearPoint Bone Screw Fiducial Kit is provided sterile and is composed of the following:

- 5x – ClearPoint Bone Screw Fiducials
- 1x – Bone Screw Fiducial holder
- 1x – Screwdriver

The Bone Screw Fiducial is made of titanium and comprised of a threaded portion that is screwed into a patient's skull and a non-threaded, exposed length that protrudes from the patient's head. The head contains a feature for compatibility with a T8 Torx screwdriver

and small divot positioned at the center of the spherical head which is used to center the pointer tip of a navigation tool.

The Bone Screw Holder is intended to assist in holding the Bone Screw Fiducials securely to the screwdriver during anchoring. This is accomplished by allowing the screwdriver to mate with the Bone Screw Fiducial without the Bone Screw Fiducial separating from the assembly therefore allowing it to be anchored to the skull.

5. INDICATIONS FOR USE

The ClearPoint Bone Screw Fiducials are intended to provide fixed reference point(s) in patients requiring stereotactic surgery in conjunction with CT imaging.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The ClearPoint Bone Screw Fiducials are substantially equivalent to the predicate device MedTronic UniBody Bone Fiducials, subject of K033619. They are identical in indications for use and both the proposed ClearPoint Bone Screw Fiducials and the predicate are bone screw fiducials made out of titanium. The devices are both comprised of a threaded portion that is screwed into a patient's skull and non-threaded, exposed length that protrudes from the patient's head and is topped by a rounded, spherical head. The top of the head of both devices is equipped with a feature for compatibility with a screwdriver.

Both the subject device and the predicate are placed orthogonally into the patient's skull prior to CT-imaging to serve as fixed reference points for registration. They are both visible under CT and a minimum of 4 of each are required for proper registration.

The difference between the ClearPoint Bone Screw Fiducials and the Unibody Bone Fiducials are minor design differences to the dimensions and the screwdriver compatibility. These differences do no introduce any risks of safety or efficacy. Table 12-1 provides a side-by-side comparison of the ClearPoint Bone Screw Fiducials to the Unibody Bone Fiducials.

Table 5-1: Side-by-side comparison of ClearPoint Bone Screw Fiducials with Predicate

	ClearPoint Bone Screw Fiducials	**Medtronic Unibody Bone Fiducials (Navigus Unibody Fiducial Marker System) K033619**	**Comparison**
Classification	21 CFR 882.4560	21CFR 882.4560	Identical
Product Code	HAW	HAW	Identical
Device Description	The ClearPoint Bone Screw Fiducials are titanium bone screw fiducials that are anchored directly to the patient's head and are used as a fixed reference point to register a pre-operative image to the optical navigation system	The Medtronic Unibody Bone Fiducials are titanium bone screw fiducials anchored directly to a patient's head and are used as fixed reference points for presurgery CT imaging for patients requiring stereotactic surgery.	Identical
Indications for Use	The ClearPoint Bone Screw Fiducials are intended to provide fixed reference point(s) in patients	The Navigus Unibody Fiducial Marker System is intended to provide fixed reference point(s) in patients requiring	Identical

	ClearPoint Bone Screw Fiducials	Medtronic Unibody Bone Fiducials (Navigus Unibody Fiducial Marker System) K033619	Comparison
	requiring stereotactic surgery in conjunction with CT imaging.	stereotactic surgery in conjunction with CT imaging.	
Principle of Operation	• A minimum of five locations for placement of the bone fiducials should be chosen. The locations should cover the entire cranium and be noncoplanar. • Bone fiducials are inserted into the bone screw holder. The bone screw holder is positioned and held to ensure the bone fiducial is placed orthogonally to the skull surface. • Using a manual or powered screwdriver the ClearPoint Bone Screw Fiducial is driven until it is flush with the skull. • This is repeated for the remaining bone fiducials. • A manual screwdriver is used to ensure each bone fiducial is fully seated. • CT imaging can then be performed to acquire the patient's CT scans	• A minimum of four locations for placement of the bone fiducials should be chosen. The locations should cover the entire cranium and be noncoplanar. • Bone fiducials are inserted through a screwdriver guide sleeve. The guide sleeve is positioned and held to ensure the bone fiducial is placed orthogonally to the skull surface. • Using a powered screwdriver with the bone fiducial is driven until it is flush with the skull. • This is repeated for the remaining bone fiducials. • A manual screwdriver used to ensure each bone fiducial is fully seated. • A protective cap is inserted over each bone fiducial. • CT imaging can then be performed to acquire the patient's CT scans.	Similar
Length	17 mm	7 mm 10 mm 13 mm	Different
Screw Head	Torx	1.6-mm cross-type blade t	Different
Materials	Bone Fiducials – Titanium Bone Screw Fiducial Holder – Polycarbonate Screwdriver – Titanium, ABS & Nylon	Bone Fiducials – Titanium Protective Caps – Thermo-plastic Screwdriver Guide – Polycarbonate	Similar
Biocompatibility	Yes	Yes	Identical
Sterile	Yes	Yes	Identical
Single Use	Yes	Yes	Identical

7. BENCH TESTING

ClearPoint Neuro has performed extensive verification testing to demonstrate that the ClearPoint Bone Screw Fiducials are as safe and effective for its intended use as the predicate device. The development of the subject device was conducted in conformance with the company's design control procedures. Design inputs provided the requirements for the respective product specifications. Design Verification testing was performed relative to these specifications. These tests included verification of physical, performance, and safety requirements, as well as simulated workflow testing for usability and effectiveness. The

results from all testing demonstrated that the ClearPoint Bone Screw Fiducials comply with all design and performance specifications.

Risk analysis was performed with mitigation of all identified risks to acceptable levels. The tests and risk analysis demonstrated that the ClearPoint Bone Screw Fiducials function as intended and are substantially equivalent to the legally marketed Medtronic Unibody Bone Fiducials.

8. CONCLUSION

The subject ClearPoint Bone Screw Fiducials and the predicate Unibody Bone Fiducials have identical indications for use and similar technological characteristics and principles of operation. ClearPoint Neuro has performed extensive bench testing to demonstrate that the differences between ClearPoint Bone Screw Fiducials and the predicate device do not raise any risks of safety or efficacy. ClearPoint Bone Screw Fiducials have been demonstrated to meet all test specifications and has been shown to be as safe, as effective, and to perform as well as the predicate device.