



January 12, 2024

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

Re: K233155  
Trade/Device Name: ClearPointer Optical Navigation Wand  
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](mailto: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  
08:21:19 -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)  
K233155

Device Name  
ClearPointer Optical Navigation Wand

Indications for Use (Describe)

The ClearPointer is intended to be used in conjunction with the SmartFrame OR System and a compatible stereotactic optical navigation system for patient registration and navigation.

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)

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## 510(k) Summary

### A. Device Information

Category	Comments
Sponsor:	ClearPoint Neuro, Inc. 6349 Paseo Del Lago Carlsbad, CA 92011
Correspondent Contact Information:	Brennan Sullivan 120 S. Sierra Ave. Solana Beach, CA 92075 617-678-1028 bsullivan@clearpointneuro.com
Device Common Name:	Neurological Stereotactic Instrument
Device Regulation & Name:	Neurological Stereotaxic Instrument, 21CFR 882.4560
Classification & Product Code:	Class II HAW
510(k) Number:	K233155
Device Proprietary Name:	ClearPointer Optical Navigation Wand

### Primary Predicate Device Information:

Predicate Device:	NexProbe Image-Guided Probe (Navigus Passive Probe, Model NP-1000)
Predicate Device Manufacturer:	Medtronic, Inc.
Predicate Device Common Name:	Neurological Stereotactic Instrument
Predicate Device Premarket Notification #	K040334
Predicate Device Classification & Name	Neurological Stereotaxic Instrument, 21CFR 882.4560
Predicate Device Classification & Product Code:	Class II HAW

### B. Date Summary Prepared

December 8, 2023

### C. Description of Device

The ClearPointer Optical Navigation Wand is an optical tracker intended to be used with the SmartFrame OR Stereotactic System and ClearPoint Bone Screw Fiducials, both of which are subject of pending 510(k) submission. The ClearPointer is used in conjunction with a Medtronic StealthStation Navigation System to align the SmartFrame OR tower to the desired

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target. It is composed of 4 optical spheres and utilizes a sphere positional geometry that is recognizable by the Medtronic StealthStation S8 Optical navigation System. It is equipped with a Pointer attachment to allow for image registration and entry point location. The Pointer Attachment can also be removed from the Optical Tracker component, so that the Tracker can be mounted to a SmartFrame OR. The SmartFrame OR Hardware Kit is provided with the following components:

- 1x ClearPointer™
- 1x Pointer Attachment
- 1x Reference Array Bracket Arm
- 1x Torx Screwdriver
- 10x Reflective Spheres

**D. Indications for Use**

The ClearPointer is intended to be used in conjunction with the SmartFrame OR System and a compatible stereotactic optical navigation system for patient registration and navigation.

**E. Comparison of Technological Characteristics**

The ClearPointer is substantially equivalent to the predicate device NexProbe, subject of K040334. The devices are similar in design in that they consist of a reference frame in a similar geometry and are assembled with 4 optical tracking spheres. They can both be attached to a stereotactic frame for registration and alignment using the Medtronic StealthStation Software and they utilize similar workflows to achieve alignment.

The differences between the devices primarily relate to the difference in stereotactic frame with which they are compatible. The ClearPointer is intended to be used with the ClearPoint SmartFrame OR System and the NexProbe is intended to be used with NexFrame. Any differences between the ClearPointer and NexProbe do not present any additional risks of safety or efficacy.

**Table 1: Side-by-side comparison of ClearPointer with Predicate Device**

	<b>ClearPointer</b>	<b>NexProbe® Image-Guided Probe (Navigus Passive Probe, Model NP-1000)</b>	<b>Comparison</b>
<b>Classification</b>	21CFR 882.4560	21CFR 882.4560	Identical
<b>Product Code</b>	HAW	HAW	Identical

## ClearPoint Neuro, Inc.

## ClearPointer

	<b>ClearPointer</b>	<b>NexProbe® Image-Guided Probe (Navigus Passive Probe, Model NP-1000)</b>	<b>Comparison</b>
<b>Indications for Use</b>	The ClearPointer is intended to be used in conjunction with the SmartFrame OR System and a compatible stereotactic optical navigation system for patient registration and navigation.	The Navigus Passive Probe is intended to be used in conjunction with the Navigus family of trajectory guides and the Medtronic StealthStation® Treatment Guidance System for patient registration and navigation. The device is provided sterile and for single use	Identical
<b>Intended Use</b>	The ClearPointer is intended for use by a Neurosurgeon in a standard operating room environment to place and orient the SmartFrame OR Tower towards a target in the brain along a planned trajectory during stereotactic functional neurosurgical procedures.	The NexProbe Image-guided Probe is intended for use by a Neurosurgeon in a standard operating room environment to place and orient the Nexframe Tower towards a target in the brain along a planned trajectory during stereotactic functional neurosurgical procedures.	Identical
<b>Materials</b>	Titanium Ti 6Al-4V Silicone PEEK Nylon 370HR composite 20% Glass-filled polycarbonate	Polymer material Stainless Steel	Similar
<b>Components</b>	ClearPointer Optical Tracker Pointer Attachment Optical Tracker Reflective Spheres Reference Array Bracket Arm T8 Torx Screwdriver	NexProbe subassembly 11.5mm passive spheres	Similar
<b>Compatibility</b>	Medtronic StealthStation S8 O-Arm® Registration PointMerge Registration	Medtronic StealthStation S8 O-Arm® Registration PointMerge Registration	Identical
<b>Single Use or Reusable</b>	Single-Use	Single-use	Identical
<b>Sterile?</b>	EtO Sterilized	Sterile	Identical

**F. Bench Testing**

ClearPoint Neuro has performed extensive testing to demonstrate that the ClearPointer is safe and effective for its intended use. The development of the ClearPointer 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 to confirm that the ClearPointer meets all design specifications. These tests included

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ClearPointer

verification of physical, performance, and safety requirements, as well as benchtop accuracy testing. Accuracy testing was performed by measuring instrument error and registration error of a simulated workflow with Stealthstation S8 software. The results are summarized in Table 2 below:

**Table 2: ClearPointer Accuracy Results**

<b>Test</b>	<b>Error</b>
Instrument Error	0.11 – 0.30 mm
Registration Error	0.2 – 0.6 mm

Risk analysis was also performed with mitigation of all identified risks to acceptable levels.

## **G. Conclusion**

The subject ClearPointer and the predicate Medtronic NexProbe 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 ClearPointer and the predicate device do not raise any risks of safety or efficacy. ClearPointer has 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.