January 12, 2024

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

Re: K233141
Trade/Device Name: SmartFrame OR
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 16:32:50 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
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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)*
K233141

Device Name
SmartFrame OR

Indications for Use *(Describe)*
The SmartFrame OR is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction with the use of a compatible optical stereotaxic navigation system using preoperative MR and/or CT imaging. These procedures include biopsies, catheter placement and electrode introduction.

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.

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ClearPoint Neuro, Inc.
SmartFrame OR

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: 510(k) Number:	Class II HAW K233155
Device Proprietary Name:	SmartFrame OR Stereotaxic System

Primary Predicate Device Information:

Predicate Device:	Medtronic NexFrame (Navigus II Trajectory Guide)
Predicate Device Manufacturer:	Medtronic, Inc.
Predicate Device Common Name:	Neurological Stereotactic Instrument
Predicate Device Premarket Notification #	K012366
Predicate Device Classification & Name	Neurological Stereotaxic Instrument, 21CFR 882.4560
Predicate Device Classification & Product Code:	Class II HAW

Reference Predicate Device Information:

Reference Device 1	
Predicate Device:	ClearPoint System (SmartFrame XG)
Predicate Device Manufacturer:	ClearPoint Neuro, Inc.
Predicate Device Common Name:	Neurological Stereotactic Instrument
Predicate Device Premarket Notification #	K222519
Predicate Device Classification & Name	Neurological Stereotaxic Instrument, 21CFR 882.4560
Predicate Device Classification & Product Code:	Class II HAW
Reference Device 2	

Predicate Device:	SmartFrame Array
Predicate Device Manufacturer:	ClearPoint Neuro, Inc.
Predicate Device Common Name:	Neurological Stereotactic Instrument
Predicate Device Premarket Notification #	K214040
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 SmartFrame OR is a hardware-only precision trajectory aiming device for procedures conducted entirely in the traditional operating room and in conjunction with commercially available optical navigation systems such as Medtronic Stealth Station S8, or functionally equivalent optical navigation systems.

The SmartFrame OR Stereotactic System tower consists of three assemblies. The reference bracket arm attaches to the skull mount and the trajectory aiming tower is attached to the mount once it is affixed to the patient skull. The ring assembly of the base is attached to the patient's skull. The socket assembly fits over the two retaining blocks on the ring assembly and is secured with the tower thumbscrews.

The SmartFrame OR Kit consists of the following Components:

- 1x SmartFrame OR Tower
- 1x Device Guide, 2.1mm
- 1x Centering Ring
- 1x Dock
- 1x Lock
- 1x Lock (2.1mm)
- 1x SNS Thumb Wheel Extension
- 1x Thumb Screw Pack

The plastic tower assembly is designed to provide multi-directional orientation adjustments to the Device Guide, which is a guide tube encased in the center of the tower assembly. The Device Guide has a 14-gauge central lumen through which a peel away sheath can be placed and oriented.

The tower, when attached to the base assembly, provides adjustments in the roll, pitch, x, and y directions by turning the appropriate thumb wheels. The thumb wheels on the SMARTFrame are used to maneuver the Device Guide by either direct or indirect physician contact.

D. Indications for Use

The SmartFrame OR is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction with the use of a compatible optical stereotaxic navigation system using preoperative MR and/or CT imaging. These procedures include biopsies, catheter placement and electrode introduction.

E. Comparison of Technological Characteristics

Medtronic's NexFrame was chosen as the predicate because its indications for use are identical to the SmartFrame OR Stereotactic System and it is similar in design and technological characteristics. There were no other potential predicate devices identified with the same indications for use or with similar design. NexFrame has been on the market for over 20 years with a history of safe and effective use. In 2019, NexFrame was subjected to a design-related recall. The recall was related to inaccuracy issues during the use of NexFrame in DBS lead implantation surgeries utilizing the auto-registration (fiducial-less) workflow. SmartFrame OR is not intended to be used in DBS procedures that utilize auto-registration. Bone screw fiducials are required to be used for registration in these procedures. For this reason, the issues leading to the recall are not applicable to the SmartFrame OR and the NexFrame remains the most appropriate predicate device.

The SmartFrame OR Stereotactic System is identical in indications for use as the Medtronic NexFrame, subject of K012719. The devices are similar in design in that they are adjustable, stereotactic frames composed of a base and a tower assembly. They allow for fine trajectory adjustments of the stereotactic frame and for the passage of neurosurgical tools through frame and into the patients brain. The devices utilize similar workflows and are both compatible with MedTronic StealthStation. Additionally, the SmartFrame OR Stereotactic System uses identical materials to the reference device SmartFrame Array and SmartFrame XG.

The differences between SmartFrame OR and the predicate consists of design modifications that allow for more precise trajectory adjustments and do not introduce any risks of safety or effectiveness. Both the proposed SmartFrame and the predicate devices allow for adjustments to the pitch and roll of the frame, however the proposed SmartFrame OR and the ClearPoint SmartFrame Array allow for changes in the X- and Y- translation of the device. Accuracy testing has been performed to demonstrate that SmartFrame OR performs as effectively as NexFrame.

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SmartFrame OR

The proposed SmartFrame OR and the primary predicate NexFrame and reference predicates ClearPoint SmartFrame XG and SmartFrame Array Systems all allow for passage of neurosurgical tools through the frame and into the patient's brain. They are all compatible with tools of different diameters via the use of adapters or guide tubes. Additionally, both the proposed SmartFrame OR and the predicate are compatible with StealthStation S8 whereas the reference predicates ClearPoint SmartFrame XG and SmartFrame Array Systems are not since those systems includes their own software. Based on these similar characteristics and verification testing performed, there are no new issues of safety or efficacy raised between the devices when used with S8. Table 1 below provides a side-by-side comparison of the proposed SmartFrame OR and the predicate device.

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Table 1: Side-by-side comparison of SmartFrame OR with Predicate and Reference Devices

	ClearPoint Neuro SmartFrame OR	Primary Predicate Medtronic NexFrame (Navigus II Trajectory Guide K012366)	Reference Predicate ClearPoint System (SmartFrame XG) K200079 and K222519	Reference Predicate SmartFrame Array K202575
Classification	21 CFR 882.4560	21CFR 882.4560	21CFR 882.4560	21CFR 882.4560
Product Code	HAW	HAW	HAW, ORR	HAW
Device Description	The SmartFrame OR Stereotactic System is a disposable, frameless, stereotactic guidance system used in conjunction with Medtronic StealthStation Navigation Systems—image-guided surgery (IGS) systems—for intracranial surgical procedures.	The NexFrame Stereotactic System is a disposable, frameless, stereotactic guidance system used in conjunction with Medtronic StealthStation Navigation Systems—image-guided surgery (IGS) systems—for intracranial surgical procedures.	The ClearPoint System is used to provide stereotactic guidance for the insertion of one or more devices into the brain within a magnetic resonance imaging (MRI) environment.	The ClearPoint System is used to provide stereotactic guidance for the insertion of one or more devices into the brain within a magnetic resonance imaging (MRI) environment
Indications for Use	The SmartFrame OR is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction with the use of a compatible optical stereotaxic navigation system using preoperative MR and/or CT imaging. These procedures include biopsies, catheter placement and electrode introduction.	The NexFrame Stereotactic System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction with the use of an Image Guided Workstation System using preoperative MR and/or CT imaging. These procedures include biopsies, catheter placement and electrode introduction. The device is ET0 sterilized and for one time use.	The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion, including deep brain stimulation (DBS) lead placement. The System is	The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion, including deep brain stimulation (DBS) lead placement. The System is

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	ClearPoint Neuro SmartFrame OR	Primary Predicate Medtronic NexFrame (Navigus II Trajectory Guide K012366)	Reference Predicate ClearPoint System (SmartFrame XG) K200079 and K222519	Reference Predicate SmartFrame Array K202575
			intended for use only with 1.5 and 3.0 Tesla MRI scanners.	intended for use only with 1.5 and 3.0 Tesla MRI scanners.
Intended Use	The SmartFrame OR Stereotactic System is intended for use by a Neurosurgeon in a standard operating room environment to guide compatible neurosurgical devices along a planned trajectory to the specified target in the brain during stereotactic functional neurosurgical procedures.	The NexFrame Stereotactic System is intended for use by a Neurosurgeon in a standard operating room environment to guide compatible neurosurgical devices along a planned trajectory to the specified target in the brain during stereotactic functional neurosurgical procedures.	The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging.	The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging.
Targeting Accuracy	±0.78 mm	±1.48 mm	±1.5mm @ ≤125mm	≤2.0 mm
Environment	Operating Room	MRI Suite or OR	MRI Suite	MRI Suite
Principal Operator	Neurosurgeon	Neurosurgeon	Neurosurgeon	Neurosurgeon
Components	SmartFrame OR Tower & Base Centering Ring Torx Screwdriver Entry Point Locator Device Guides / Adapters	Nexframe socket and ring assemblies Center alignment and multilumen adapters Offset alignment and multilumen adapters.	SmartFrame XG, Scalp Mount Base, Bone Screws, Stand-Off Pins, Screwdriver, Centering Tool, Wharen Centering Guide (packaged and sold separately), Dock and Lock, Roll Lock Screw with Washer, Rescue Screws (packaged separately)	SmartFrame Array, Scalp Mount Base, Bone Screws, Stand-Off Pins, Screwdriver, Centering Tool, Wharen Centering Guide (packaged and sold separately), Dock and Lock, Roll Lock Screw with Washer, Rescue Screws (packaged separately)
Materials	20% Glass-Filled Polycarbonate Titanium (Ti-6Al-4V per ASTM F136) Silicone Nylon Polycarbonate PEEK	Polycarbonate Silicone Rubber Titanium Stainless Steel Acetal Nylon Other polymer materials	Polycarbonate Silicone Rubber Titanium Stainless Steel Acetal Nylon Other polymer materials	Polycarbonate Silicone Rubber Titanium Stainless Steel Acetal

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	ClearPoint Neuro SmartFrame OR	Primary Predicate Medtronic NexFrame (Navigus II Trajectory Guide K012366)	Reference Predicate ClearPoint System (SmartFrame XG) K200079 and K222519	Reference Predicate SmartFrame Array K202575
	Acetal Ultem-1000 PTFE Kapton			Nylon Other polymer materials
Principle of Operation	Patient Scanning MRI for planning CT for registration Surgical Planning Select target location Select entry point Optional Non-Sterile Registration IGS System Setup and Sterile Registration	Patient Scanning MRI for planning CT for registration Surgical Planning Select target location Select entry point Optional Non-Sterile Registration IGS System Setup and Sterile Registration	Patient Scanning MRI for planning MRI for registration Surgical Planning Select target location Select entry point MRI Registration IGS System Setup and Sterile Registration	Patient Scanning MRI for planning MRI for registration Surgical Planning Select target location Select entry point MRI Registration IGS System Setup and Sterile Registration
Range of Motion	Pitch - ±33° Roll: ±26° X-translation: ±2.5mm Y-translation: ±2.5mm	Angulation: ±25° Rotation: 360°	Pitch - ±33° Roll: ±26° X-translation: ±2.5mm Y-translation: ±2.5mm	Pitch - ±33° Roll: ±26°
Burr Hole	14mm or drill bit when appropriate	14mm	14mm or drill bit when appropriate	14mm or drill bit when appropriate
Sterile	Yes	Yes	Yes	Yes
Single Use	Yes	Yes	Yes	Yes
Multi-lumen spacing	Continuous XY-stage	2 mm	Continuous XY-stage	3-mm center-to-center virtual offset array

F. Bench Testing

ClearPoint Neuro has performed extensive testing to demonstrate that the SmartFrame OR System is safe and effective for its intended use. The modifications implemented in SmartFrame OR System were 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 benchtop accuracy testing. The navigational accuracy validation values and how they compare to the predicate device are presented in the table below.

Table 1: Accuracy Performance Comparison*

Device	Positional Error (mm)			Trajectory Angle Error (degrees)		
	Mean	Standard Deviation	99% CI* Upper Bound	Mean	Standard Deviation	99% CI* Upper Bound
SmartFrame OR	1.36	0.86	1.57	0.67	0.46	0.92

*Measurement tools used in accuracy testing were found to add up to a 0.25 mm differential to results. To represent worst case of this measurement error, this 0.25 mm has been added to the results in Table 1.

Risk analysis was performed with mitigation of all identified risks to acceptable levels. The tests and risk analysis demonstrated that the SmartFrame OR System functions as intended and is substantially equivalent to the legally marketed Medtronic NexFrame.

G. Conclusion

The subject SmartFrame OR and the predicate NexFrame have the 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 SmartFrame OR and the predicate device do not raise any risks of safety or efficacy. SmartFrame OR 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.