September 16, 2022

ClearPoint Neuro, Inc.
% John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K222519
Trade/Device Name: ClearPoint System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, ORR
Dated: August 19, 2022
Received: August 19, 2022

Dear Dr. Smith:

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)*
K222519

Device Name

ClearPoint System (version 2.1)

Indications for Use *(Describe)*

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 intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices.

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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510(k) Summary
ClearPoint Neuro, Inc.'s ClearPoint System

1. Submitter's Contact Information

Company Name	Hogan Lovells, US LLP
Address	555 Thirteenth Street, NW Washington, DC 20004
Telephone	202-637-5600
Fax	202-637-5910
Contact	John J. Smith, M.D., J.D.
E-mail	John.smith@hoganlovells.com
Date Prepared	September 16, 2022

2. Sponsor Contact Information

Company Name	ClearPoint Neuro, Inc.
Address	ClearPoint System™ ClearPoint Neuro, Inc. 5 Musick Irvine, CA 92618
Contact	Mary McNamara-Cullinane, VP, Regulatory Affairs

3. Device Name

Common Name	Neurological Stereotaxic Instrument
Proprietary Name	ClearPoint System
Classification	21 C.F.R. § 882.4560
Regulatory Class	II
Product Code	ORR, HAW

4. Predicate Device: ClearPoint Neuro, Inc. ClearPoint System (K181195)

5. Device Description

The ClearPoint System is essentially identical from a technological standpoint to the cleared predicate device described in K181195 (ClearPoint System). The company has made updates that are limited to the software of the ClearPoint System described in K181195 (predicate device). Specifically, the company has released an updated version of software 2.0, which was part of the last clearance, and has now been upgraded to software 2.1. The hardware and Indications for Use are unchanged from the device described in K181195.

The ClearPoint System is comprised of a workstation laptop with software, the SMARTGrid™ MRI Guided Planning Grid, the SMARTFrame™ MRI-Guided Trajectory Frame, the SMARTFrame™ Accessory Kit and the SMARTFrame™ Thumbwheel Extension.

The SMARTGrid and associated Marking Tool are designed to assist the physician to precisely position the entry hole as called out in the trajectory planning software. The SMARTFrame is an Adjustable Trajectory Frame (ATF) that provides the guidance and fixation for neurosurgical tools. The MRI visible fluids of the Targeting Cannula along with the fiducial markers in the base of the frame allows for trajectory feedback when the physician views the MRI images, makes changes and confirms with subsequent MR images.

The modified ClearPoint Software is used to provide stereotactic guidance for the insertion of one or more devices into the brain within a magnetic resonance imaging (MRI) environment, using hardware provided by ClearPoint Neuro, Incorporated. The software will guide the end user through a set of discrete workflow steps for identifying localization hardware mounted onto the patient, planning one or more trajectory paths into the brain, guiding the alignment of one or more stereotactic frames along each of the planned trajectories, and monitoring the insertion of one of more devices into the brain. The software also supports workflow for creating pre-operative plans prior to carrying out the intra-operative procedure.

The software will be installed on a physical laptop computer situated inside the MRI Suite during the intra-operative procedure. There, it will be used in conjunction with a MRI scanner, the SMARTFrame adjustable trajectory frame (ATF), and associated disposable hardware kits provided by ClearPoint Neuro to guide the user through the insertion of one or more devices into the brain. Throughout the procedure, in instances where specific scans are required, the software application will prescribe scan plane parameters detailing the position and angulation of a desired image acquisition necessary to proceed with the workflow. In these cases, users are required to enter the parameters prescribed by the software manually on the MRI scanner console to carry out the appropriate image acquisition.

The ClearPoint System can be used with any MRI-compatible head fixation frame to immobilize the patient's head with respect to the scanner table, as well as with any imaging coil(s) (supplied by scanner manufacturers) that meet the physician's desired imaging quality. ClearPoint Neuro also supplies an optional head fixation frame that can be used with the ClearPoint System.

The ClearPoint Workstation includes the following:

1. ClearPoint Workstation Software (for trajectory planning and monitoring)
2. Laptop Computer

The hardware components of the current ClearPoint System are the SMARTFrame and Accessories. They are all single use devices that are provided sterile. They include the following:

1. SMARTGrid MRI Planning Grid (interacts with the software to determine the desired location of the burr hole)
    a. Marking Grid
    b. Marking Tool
2. SMARTFrame Pack (SMARTFrame or SMARTFrame XG)
    a. SMARTFrame ("ATF") with Base
    b. Centering Device and Wharen Centering Guide
    c. Dock

    d. Device Lock (2 different diameters)
    e. Screwdriver
    f. Roll Lock Screw and Washer
3. Rescue Screws (Extra Titanium Screws)
4. Thumbwheel Extension
5. Accessory Kit
    a. Peel-away Sheath
    b. Stylet
    c. Lancet
    d. Depth Stop
    e. Ruler
6. Scalp Mount Base
7. Guide Tubes and Device Guide Packs (Guide Cannulas)

In addition, the ClearPoint System is used with the following separately cleared or Class I, 510(k)-exempt products:

- SmartTip MRI Hand Drill and Drill Bit Kit
- MRI Neuro Procedure Drape, with Marker Pen and Cover
- SmartFrame MR Fiducial

6. Indications for 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 intended for use only with 1.5 and 3.0 Tesla MRI scanners.

7. Summary of Technological Characteristics of the Device Compared to the Predicate Device

The purpose of this 510(k) Notice is to incorporate an update to the ClearPoint System software from version 2.0 to 2.1.

Table 1: Substantial Equivalence of the Subject Device as Compared to Predicate Device

	ClearPoint System Modified Device (subject)	ClearPoint System (predicate)
Classification	21 C.F.R. 882.4560	21 C.F.R. 882.4560
Product Code	ORR, HAW	ORR, HAW

	ClearPoint System Modified Device (subject)	ClearPoint System (predicate)
Intended 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 intended for use only with 1.5 and 3.0 Tesla MRI scanners.	The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during the 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 intended for use only with 1.5 and 3.0 Tesla MRI scanners.
Environment	MRI Suite	MRI Suite
Sterilization	EO 10-6 SAL	EO 10-6 SAL
SmartGrid Pack	MRI Planning Grid & Marking Tool	MRI Planning Grid & Marking Tool
SmartFrame Pack	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 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)
Hand Controller	Thumbwheel Extension (Light Hand Controller)	Thumbwheel Extension (Light Hand Controller)
Accessory Kit	Peel-away Sheath, Lancet, Stylet, Depth Stop, Ruler	Peel-away Sheath, Lancet, Stylet, Depth Stop, Ruler
Drill Guides	4.5mm & 6.0mm	4.5mm & 6.0mm
Targeting Cannula ID	0.0825”	0.0825”
Targeting Cannula Material	Ultem and PEEK	Ultem and PEEK
Guide Tube/Device Guide/Drill Guide	0.0938, 0.141, 0.191, 0.250”	0.0938, 0.141, 0.191, 0.250”
Guide Tube/Device Guide/Drill Guide Material	UItem	UItem

	ClearPoint System Modified Device (subject)	ClearPoint System (predicate)
Packaging	Sterile, Sealed Tray, Inside Sterile Tyvek Pouch (Wharen Centering Guide and Drill and Device Guides are Sterile in a double Tyvek Pouch Without a Tray; Wharen Centering Guide Packaging includes PVC)	Sterile, Sealed Tray, Inside Sterile Tyvek Pouch (Wharen Centering Guide and Drill and Device Guides are Sterile in a double Tyvek Pouch Without a Tray; Wharen Centering Guide Packaging includes PVC)
Targeting Accuracy	±1.5mm @ ≤125mm	±1.5mm @ ≤125mm
Software	2.1	2.0
Operating System	Windows 10	Windows 10
Programming Languages	Visual C# Visual C++	Visual C# Visual C++
Visualization Software Toolkit	Fovia HDVR®	Fovia HDVR®
DICOM Toolkit	MergeCOM-3 Dicom Toolkit®	MergeCOM-3 Dicom Toolkit®
DICOM Features	• Retrieval of images from MR scanner through network (TCP/IP) • Browse/load images from media/local storage • Configuration and testing of image transfer from scanner to workstation • Load enhanced/compressed DICOM images	• Retrieval of images from MR scanner through network (TCP/IP) • Browse/load images from media/local storage • Configuration and testing of image transfer from scanner to workstation
Image Registration Framework	Insight Toolkit (ITK)	CCR NeuroTargeting Registration Library

	ClearPoint System Modified Device (subject)	ClearPoint System (predicate)
Image Fusion/Registration	• Ability to automatically register/fuse MR-to-MR and MR-to-CT images acquired in different frames of reference • Ability to seed automatic registration/fusion based on an initial input transform. • Slider control used to set the relative weight of the two blended image volumes • Tools for reviewing the accuracy of registration and manual override capabilities	• Ability to automatically register/fuse MR-to-MR and MR-to-CT images acquired in different frames of reference • Slider control used to set the relative weight of the two blended image volumes • Tools for reviewing the accuracy of registration and manual override capabilities
Volume of Interest Definition	• Ability to define and visualize 3D structures within a loaded image set • Tools for defining 3D volumes of interest manually • Display and computation of volume interest measurements (e.g., total volume, volume overlap)	• Ability to define and visualize 3D structures within a loaded image set • Tools for defining 3D volumes of interest manually • Semi-automatic segmentation of structures with visible borders (e.g., anatomical structure, tumor/lesion, or infusion volume) • Display and computation of volume interest measurements (e.g., total volume, volume overlap)

	ClearPoint System Modified Device (subject)	ClearPoint System (predicate)
Image Segmentation Algorithms	• Algorithm to automatically identify anterior commissure (AC) and posterior commissure (PC) locations within the brain. This algorithm has the same implementation as in the predicate device • Algorithms to automatically locate and identify marking grid, targeting frame components, cannula and device tip. These algorithms have the same implementation as in the predicate device	• Algorithm to automatically identify anterior commissure (AC) and posterior commissure (PC) locations within the brain. This algorithm has the same implementation as in the predicate device • Algorithms to automatically locate and identify marking grid, targeting frame components, cannula and device tip. These algorithms have the same implementation as in the predicate device
Scan Plane Parameters	Geometric computations to display position and orientation of prescribed scan plane parameters for Siemens, Philips and GE MR scanner manufacturers. These computations are the same as in the predicate device.	Geometric computations to display position and orientation of prescribed scan plane parameters for Siemens, Philips and GE MR scanner manufacturers. These computations are the same as in the predicate device.
Hardware Adjustment Computations	Computations used to indicate required frame adjustments needed to adjust cannula to desired trajectory. These computations are the same as in the predicate device.	Computations used to indicate required frame adjustments needed to adjust cannula to desired trajectory. These computations are the same as in the predicate device.
Low-Level Math Library	Low-level math utilities used for geometric computations. These utilities are the same as in the predicate device.	Low-level math utilities used for geometric computations. These utilities are the same as in the predicate device.
Workflow	Device depth values for all frame are shown simultaneously in pop-up dialog illustrating how to prepare the device(s) for insertion.	Device depth values are displayed in step panel for the currently selected frame.
	Output procedure reports in Open XML Paper Specification (XPS) and Portable Document Format (PDF).	Output procedure reports in Open XML Paper Specification (XPS).

8. Testing to Support the Software Modifications:

Based on the company's Software Requirements Specification (SRS), the company performed verification testing for all software changes in the ClearPoint 2.1 software release. Each element of the SRS was tested and found to meet the requirements. In addition, a complete validation and verification of the ClearPoint system was conducted, the results of which were provided in applicable test reports. Results of the software verification and validation activities demonstrate compatibilities with the requirements of the IEC 62304 standard. Risk analysis activities were also performed in compliance with requirements of ISO 14971:2019. The testing performed is summarized below.

Non-Clinical Testing:

Regression Testing
System regression tests were performed to verify that there are no regressions in existing functionality in the ClearPoint 2.1 software as compared to the predicate ClearPoint System 2.0 (K181195)
software as follows:

Head-To-Head Comparison: This manual test verifies that given identical input, the output from the ClearPoint 2.1 is consistent with the predicate ClearPoint System 2.0 software version. ClearPoint 2.1 passed successfully which verified that no unintended changes have been introduced from the previous version in essential features that are not expected to have changed.

Image Registration Unit Test: This automated unit test compares ClearPoint 2.1 image registrations to image registrations achieved using the predicate ClearPoint System 2.0 software version. ClearPoint 2.1 passed successfully which verified that users will not be required to perform large manual registrations more often than in the previous version.

Automated Testing
An automated test suite was executed which cover a subset of functionality for which pass/fail can be determined by a test script without human intervention and where corresponding manual testing would be effort-intensive or otherwise problematic to achieve manually. These tests can be organized into the following groupings:

a. UI Automation: This section contains Automated UI tests that interact with the software application through its user interface in much the same manner as a live user would, but because it is scripted, reproducible results are assured.
b. Segmentation: This test suite exercises all the underlying segmentation algorithms in isolation outside the application against a range of data inputs and compares the output to known expected results
c. Unit: These are general unit tests that exercise low-level math and other libraries in isolation outside of the application. Testing outside the application permits testing with a broader range of inputs that are not readily reproduced inside the application.

All automated tests were executed with no failures and no incidental observations.

Integrated System Testing
Integrated system tests were performed using the ClearPoint 2.1 software, ClearPoint disposable hardware and an MRI scanner to reproduce clinical usage. The tests were executed once for each support scanner manufacturer: Philips, Siemens and General Electric. The tests focused on those

system requirements that require a live connection with a MR scanner for verification. The tests were also used to verify that the ClearPoint 2.1 software is able to guide placement of a device within the defined accuracy specifications of the system. All tests were executed and pass results were obtained.

Manual Testing

Manual verification bench tests were performed to evaluate all remaining requirements not explicitly covered by other test activities. This includes any tests which are not readily automated or for which human observation and/or interaction is sought. Tests were executed by a tester interacting with the running software using previously acquired test image data to reproduce the conditions of clinical usage. The manual verification tests were executed independently by two different testers using the same build of software. All tests were executed with no failures and no incidental observations.

9. Conclusions:

The ClearPoint System's software update to version 2.1 is as safe and effective as the predicate device, the ClearPoint System. The ClearPoint System's software modification has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. In particular, the software modification in the subject device contains the same software workflow, materials, design, energy source, and principles of operation of the predicate device. The minor differences between the subject and predicate device do not raise any new issues of safety and effectiveness when the device is used as labeled, and the design controls and data collected ensure no adverse impact on safety or effectiveness. Therefore, it can be concluded that the ClearPoint System's software update to version 2.1 is substantially equivalent to the ClearPoint System predicate device.