April 12, 2022

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

Re: K214040
Trade/Device Name: ClearPoint Array System (version 1.1)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: February 11, 2022
Received: February 11, 2022

Dear John 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)*
K214040

Device Name

ClearPoint Array System (version 1.1)

Indications for Use *(Describe)*

The ClearPoint Array 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 Array 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 Array System (version 1.1)

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared:

ClearPoint Neuro Inc.
5 Musick
Irvine, CA 92618
Phone: (949) 900-6833
Facsimile: (888) 979-8369
Contact Person: Megan Faulkenberry, VP Quality & Regulatory

Date Prepared: April 12, 2022

Name of Device: ClearPoint Array System (version 1.1)

Common or Usual Name: ClearPoint Array System

Classification Name: Neurological Stereotaxic Instrument, 21 CFR 882.4560

Regulatory Class: Class II

Product Code: HAW

Predicate Device:

ClearPoint Array System (K202575)

Intended Use / Indications for Use

The ClearPoint® Array 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 ® Array 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.

Device Description

The ClearPoint Array System is comprised of a workstation laptop with workstation software, the SMARTGrid™ MRI-Guided Planning Grid, the SMARTFrame™ Array MRI-Guided Trajectory Frame, SmartFrame Array Reducer Tube Kit, the ClearPoint™ Accessory Kit, the SMARTFrame™ Array Thumb Wheel Extension Set, and the MRI Neuro Procedure Drape.

A pre-alignment may be used when it is desired to obtain an approximate alignment using a Surgical Navigation System prior to performing final alignment and device placement in the MR Scanner using real-time MR Images. Pre-alignment using an SNS is not intended to provide accurate stereotactic placement. The final alignment and insertion must be performed

using real-time MR images with ClearPoint Array software prior to inserting a device in the brain. The SMARTGrid™ MRI-Guided Planning Grid 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™ Array MRI-Guided Trajectory Frame is an adjustable trajectory frame that provides the guidance and fixation for neurosurgical tools. MRI visible fluids in the Targeting Stem along with the fiducial markers in the base of the frame allows for trajectory feedback when the physician views the MR images, makes changes and confirms the subsequent MR images. The ClearPoint Array 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 Array System.

The ClearPoint System Array Workstation includes the following:

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

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

1 SMARTFrame Array Pack
   a. SMARTFrame Array (adjustable trajectory frame to guide and hold the neurosurgical tools, includes Probe Adapter and Tracker Rod)
   b. SMARTFrame Array Scalp Mount Base (includes fiducials, titanium screws, and support pins)
   c. Entry Point Locator
   d. Targeting Stem
   e. Centering Device
   f. Dock
   g. Device Lock (2 different diameters)
   h. Screwdriver
   i. 2.1-mm Guide Tube
   j. 4.5 Center Drill Guide
   k. 4.5 Offset Drill Guide
   l. 3.4-mm Drill Reducer Tube
   m. Center Insertion Guide
   n. Offset Insertion Guide

2 SmartFrame Array Thumb Wheel Extension Set for the trajectory frame

3 SmartFrame Array Guide Tube Kit
   a. 1.7-mm Guide Tube
   b. 2.5-mm Guide Tube and Device Lock

c. 3.2-mm Guide Tube and Device Lock

4 SmartFrame Array Guide Tubes (sold seperately)
   a. 7.9mm Center and Offset Device Guides
   b. 5.4mm Center and Offset Device Guides

Common components to ClearPoint System include:

1. SMARTGrid Pack (interacts with the Software to determine the desired location of the burr hole):
   a. Marking Grid
   b. Marking Tool

2. Accessory pack:
   a. Peel away sheath
   b. Stylet
   c. Depth Stop
   d. Ruler

3. MRI Neuro Procedure Drape

Summary of Technological Characteristics

The purpose of this 510(k) notice is to incorporate an update to the ClearPoint Array software. The updated version of the software includes a preoperative planning module. This optional step in the clinical workflow involves planning one or more trajectory paths into the brain prior to the day of surgery, using previously acquired images of the patient.

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

	ClearPoint Array System (K202575)	**ClearPoint Array System (v1.1) (Subject Device)**
Classification	21 C.F.R. § 882.4560	21 C.F.R. § 882.4560
Product code	HAW	HAW
Intended Use	The ClearPoint® Array 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® Array 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.	The ClearPoint® Array 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® Array 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.
Environment	MRI Suite or OR	MRI Suite or OR
Sterilization	EO 10^{-6} SAL	EO 10^{-6} SAL
SMARTGrid Pack	MRI Planning Grid & Marking tool	MRI Planning Grid & Marking tool
SMARTFrame Pack	SMARTFrame Array Adjustable Trajectory Frame, Scalp Mount Base, Entry Point Locator, Targeting Stem, Centering Device, Dock, Device Lock, screwdriver, 2.1-mm Guide Tube, Center Drill Guide, Offset Drill Guide, 3.4-mm Drill Reducer Tube, Center Insertion Guide, Offset Insertion Guide	SMARTFrame Array Adjustable Trajectory Frame, Scalp Mount Base, Entry Point Locator, Targeting Stem, Centering Device, Dock, Device Lock, screwdriver, 2.1-mm Guide Tube, Center Drill Guide, Offset Drill Guide, 3.4-mm Drill Reducer Tube, Center Insertion Guide, Offset Insertion Guide
Hand Controller	Thumbwheel Extension	Thumbwheel Extension
Accessory pack	Peel away sheath, Stylet, Depth stop, ruler	Peel away sheath, Stylet, Depth stop, ruler
Drill Guides	Drill Guide, 4.5-mm (included in SMARTFrame Pack)	Drill Guide, 4.5-mm (included in SMARTFrame Pack)
Targeting Cannula ID	No ID, Targeting Stem is completely fluid-filled	No ID, Targeting Stem is completely fluid-filled
Targeting Cannula Material	PEEK	PEEK
Guide Tube/Device Guide/Drill Guide ID	Drill Guide ID: 4.5 mm (included in SmartFrame Pack) Drill Guide Tube ID: 3.4 mm (included in SmartFrame Pack) Guide Tube ID: 3.2 mm	Drill Guide ID: 4.5 mm (included in SmartFrame Pack) Drill Guide Tube ID: 3.4 mm (included in SmartFrame Pack) Guide Tube ID: 3.2 mm

	Guide Tube ID: 2.5 mm Guide Tube ID: 2.1 mm Guide Tube ID: 1.7 mm	Guide Tube ID: 2.5 mm Guide Tube ID: 2.1 mm Guide Tube ID: 1.7 mm
Packaging	SMARTFrame Array Pack: PETG Tray with sealed Tyvek Lid inside of a Sealed Mylar-Tyvek Pouch SMARTFrame Array Thumbwheel Extension: PETG Tray sealed in a Double Mylar-Tyvek Pouch SMARTFrame Array Guide Tube Kit: Sealed Double Mylar-Tyvek Pouches	SMARTFrame Array Pack: PETG Tray with sealed Tyvek Lid inside of a Sealed Mylar-Tyvek Pouch SMARTFrame Array Thumbwheel Extension: PETG Tray sealed in a Double Mylar-Tyvek Pouch SMARTFrame Array Guide Tube Kit: Sealed Double Mylar-Tyvek Pouches
Targeting Accuracy	≤ 2.0 mm	≤ 2.0 mm
Software	ClearPoint Array 1.0.x	ClearPoint Array 1.1.x

Substantial Equivalence

The company completed new software validation for the ClearPoint Array version 1.1 software update, which includes the addition of the preoperative planning module.

The ClearPoint Array System has the same intended use and indications for use, similar technological characteristics and principles of operation as the predicate ClearPoint Array System. The addition of the preoperative planning module to the ClearPoint Array software does not raise new and different questions of safety and effectiveness.

Conclusions

The ClearPoint Array System is as safe and effective as the predicate device. The ClearPoint Array System has the same indications for use, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between the subject device and its predicate devices raise no new issues of safety or effectiveness. Thus, the ClearPoint Array System is substantially equivalent to the predicate device.