September 15, 2023

ClearPoint Neuro, Inc.
Brennan Sullivan
Regulatory Affairs Manager
5 Musick
Irvine, California 92618

Re: K232102
Trade/Device Name: ClearPoint Array System (Version 1.2)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: August 18, 2023
Received: August 18, 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 (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 -S

Digitally signed by Adam D. Pierce -S
Date: 2023.09.15 16:20:45 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
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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)*
K232102

Device Name
ClearPoint Array System (Version 1.2)

Indications for Use *(Describe)*
The ClearPoint Array System (Version 1.2) 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 (Version 1.2) 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
for the ClearPoint Neuro
ClearPoint Array System (Version 1.2)

1. SUBMITTER/510(K) HOLDER

ClearPoint Neuro, Inc.
5 Musick
Irvine, CA 92618
Contact Person: Mary McNamara-Cullinane
Telephone: 508-446-1830

Date Prepared: August 18, 2023

2. DEVICE INFORMATION

Name of Device:	ClearPoint Array System (Version 1.2)
Common or Usual Name:	ClearPoint Array System
Classification:	Neurological Stereotaxic Instrument, 21CFR 882.4560
Regulatory Class:	Class II
Product Code	HAW

3. PREDICATE DEVICES

- ClearPoint Array System 1.1 Software K214040
- ClearPoint Array System 1.0 Software K202575

4. 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. The ClearPoint Array Workstation includes the following:

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

The hardware components of the ClearPoint Array System are the SMARTFrame Array and accessories, and are listed below. They are all single use devices provided sterile. Beyond the changes described above, there have been no modifications to the hardware compared to the last cleared version of the device (K214040).

1. SMARTFrame Array Pack

   a. SMARTFrame Array (adjustable trajectory frame to guide and hold the neurosurgical tools, includes Probe Adapter, Tracker Rod)
   b. SMARTFrame Array Scalp Mount Base (includes fiducials, titanium screws, and titanium standoff 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. 0.5-mm Guide Tube and Device Lock
   c. 3.1-mm Guide Tube and Device Lock
   d. SmartFrame Array Guide Tubes (sold separately)
   e. 7.9mm Center and Offset Device Guides
   f. 5.4mm Center and Offset Device Guides

Common Components to the ClearPoint System are listed below. These components have not been modified since their clearance (K214040, K200097, K100836, K091343).

1. SMARTGrid Pack (interacts with the Software to determine the desired location of the burr hole) (K100836)
   a. Marking Grid
   b. Marking Tool
2. Accessory Pack (K200097)
   a. Peel away sheath
   b. Stylet
   c. Depth Stop
   d. Ruler
3. MRI Neuro Procedure Drape (K091343)

5. INTENDED USE

The ClearPoint® Array System (Version 1.2) 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 (Version 1.2) 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.

6. NON-CLINICAL TESTING

ClearPoint Neuro performed extensive Non-Clinical Verification Testing to evaluate the safety and performance of the software components of ClearPoint Array System (Version 1.2). The following software verification testing was performed:

- Automated Verification
- Integrated System Verification
- Localization Verification
- Regression Test Verification

The results of all testing met the acceptance criteria and demonstrated that the modified ClearPoint Array Software complies with all design specifications and performs as expected.

Accuracy testing was performed to confirm that modifications included in ClearPoint Array 1.2 did not cause any unexpected changes in the accuracy specifications of the software, with successful results. Table 5-1 outlines the demonstrated accuracy specifications of ClearPoint Array System.

Table 5-1: ClearPoint Array Accuracy Specifications

Performance Validation	Positional Error (mm)			Angular Error (deg.)		
ClearPoint Array System	Mean (x,y,z)	Std. Dev.	99% CI	Mean	Std. Dev.	99% CI
	0.78 1.52 -1.41	0.39 0.46 0.73	1.14 1.94 -2.08	0.67°	0.14°	0.85°

*CI = confidence interval

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of the Array 1.2 Software are essentially identical to the predicates. The purpose of this Special 510(k) is to incorporate an update to the ClearPoint Array software. In addition to the functions of the predicate device, the ClearPoint Array System (Version 1.2) software includes the following modifications:

- Support for parallel trajectory planning and realization using the guide channels of the ClearPoint Array® frame, such that devices can be inserted using guide channel positions without the need to adjust the frame angulation between insertions. This feature set includes:
  - Ability to define one or more parallel trajectory paths corresponding to physical guide channels on the frame.

  - Capabilities to visualize the pre-mount orientation of the frame base(s) needed to achieve the parallel trajectories corresponding to the guide channel positions.
  - Prescription of adjustments needed to align the frame(s) along any parallel trajectory path.
  - Instructions for inserting device(s) along one or more parallel trajectory paths.
- Improved trajectory definition and review tools, including the ability to visualize pre-operatively planned trajectories in a three-dimensional scene, ability to modify target/entry points using coordinate values and ability to copy previously defined trajectory paths.
- Image visualization and rendering performance improvements.
- Improved automatic fusion of image sets that are acquired in different frames of reference.
- A new set of interactive viewport tools which provide a richer functional toolset offering.
- Translating the software user interface to support nine additional languages.

There have been no modifications to any of the hardware components of the predicate device. In addition, the minor differences in the newer software version do not alter the fundamental clinical purpose or present different questions of safety or effectiveness as compared to the predicate. The final software version has been fully validated. Thus, the ClearPoint Array System (version 1.2) is substantially equivalent to the ClearPoint Array System (K214040).The ClearPoint Array System (version 1.2) is substantially equivalent to the predicate The ClearPoint Array System (K214040) because the subject device raises no new issues of safety and effectiveness, meets all test specifications, and the non-clinical testing performed demonstrates that the subject devices is as safe, as effective, and performs as well as the predicate device. A side-by-side comparison of the subject device to the predicate can be found below in Table 5-2.

Table 5-2: Side-by-side comparison of ClearPoint Array 1.2 Software with Parent Device

Characteristic	Proposed ClearPoint Array System (v1.2)	ClearPoint Array System (v1.1) K214040
Classification	21 C.F.R. § 882.4560	21 C.F.R. § 882.4560
Product Code	HAW	HAW
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	Identical

	MR Conditional implants and devices.	
Environment	MRI Suite or OR	Identical
SMARTGrid Pack	MRI Planning Grid & Marking tool.	Identical
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	Identical
Hand Controller	Thumbwheel Extension	Identical
Accessory pack	Peel away sheath, Stylet, Depth stop, ruler	Identical
Drill Guides	Drill Guide, 4.5-mm (included in SMARTFrame Pack)	Identical
Targeting Cannula ID	No ID, Targeting Stem is completely fluid-filled	Identical
Targeting Cannula Material	PEEK	Identical
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 Guide Tube ID: 2.5 mm Guide Tube ID: 2.1 mm Guide Tube ID: 1.7 mm	Identical
Targeting Accuracy	≤ 2.0 mm	Identical
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	Identical
Software	Version 1.2	Version 1.1
Operating System	Windows 10, Windows 11	Windows 10
Programming Languages	Visual C# Visual C++	Identical
Visualization Software Toolkit	Fovia HDVR®	Identical
DICOM Toolkit	MergeCOM-3 Dicom Toolkit®	Identical
Image Registration Framework	Insight Toolkit (ITK)	CCR NeuroTargeting Registration Library

8. CONCLUSIONS

The ClearPoint Array System (Version 1.2) is as safe and effective as the predicate device. The ClearPoint Array System (Version 1.2) 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 (Version 1.2) is substantially equivalent to the predicate device.