January 22, 2021

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

Re: K202575
Trade/Device Name: ClearPoint Array System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: December 23, 2020
Received: December 23, 2020

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)*

K202575

Device Name

ClearPoint Array System

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

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

ClearPoint Neuro Inc.
5 Musick
Irvine, CA 92618
Phone: (949) 900-6833
Facsimile: (49) 900-6834
Contact Person: Peter Piferi, C.O.O
Date Prepared: January 22, 2021

Name of Device: ClearPoint Array System

Common or Usual Name: ClearPoint Array System

Classification Name: Neurological Stereotaxic Instrument, 21 CFR 882.4560

Regulatory Class: Class II

Product Code: HAW

Predicate Devices

ClearPoint System and Accessories (K200079)

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. Some of the accessories are common components with the ClearPoint System (K200079). 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. Center Drill Guide
   k. 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

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

Technological Characteristics

The purpose of the 510(k) is to modify the SmartFrame Array by:

1. Material change and addition of small geometric features on the Adjustable Trajectory Frame (ATF) and Scalp Mount Base.
2. Replacing the ATF's continuous X-Y adjustment with a discrete positional adjustment.
3. Modification of the targeting cannula material and construction.
4. Providing a passive guide and rod with the ATF that allows users to insert a surgical navigation system Probe or Universal Tracker and be held in the ATF.
5. Minor updates to device packaging.
6. Software modifications for:
   - New workflow options, user interface, image alignment methods.
   - Introduction of new software tools for volume of interest comparison.

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

	ClearPoint System (Predicate) K200079	**ClearPoint Array System (Subject)**
Classification	21 C.F.R. § 882.4560	21 C.F.R. § 882.4560
Product code	HAW	HAW
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® Array System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode	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

	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.	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	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 XG Adjustable Trajectory Frame with Targeting Cannula, Skull Mount Base, Screwdriver, Dock, Device Lock, Centering Ring	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, 3.4-mm Drill Guide, 4.5-mm Drill Guide, 6.0-mm	Drill Guide, 4.5-mm (included in SMARTFrame Pack)
Targeting Cannula ID	.083” (2.1 mm)	No ID, Targeting Stem is completely fluid-filled
Targeting Cannula Material	Ultem and PEEK	PEEK
Guide Tube/Device Guide/Drill Guide ID	Drill Guide ID: 4.5 mm Drill Guide ID: 6.0 mm Device/Drill Guide ID: 3.4 mm Device Guide ID: 3.2 mm Device Guide ID: 2.5 mm Device Guide ID: .093” Guide Tube ID: 1.7 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
Packaging	SMARTFrame Pack: PETG Tray with sealed Tyvek Lid inside of a Sealed Mylar-Tyvek Pouch Thumbwheel Extension: PETG Tray sealed in a Double Mylar-Tyvek Pouch Guide Tubes and Drill Guides: 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	≤ 1.5 mm	≤ 2.0 mm
Software	ClearPoint 2.0.x	ClearPoint Array 1.0.x

Biocompatibility

All patient contacting components remain the same as the predicate ClearPoint System except for the SMARTFrame Array Base. For this reason, biocompatibility was only performed on the SMARTFrame Array Base. The SmartFrame Lite Base was found to be biocompatible per ISO 10993-1 as summarized below.

Test Description	Results	Pass/Fail
Cytotoxicity ISO 10993-5	The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).	Pass
Irritation ISO 10993-11	There was no erythema and no edema observed on the skin of the animals treated with the Saline and Sesame Oil extracts. For both test article extracts, the Primary Irritation Index was calculated to be 0.0 and the irritation response was categorized as negligible.	Pass
Sensitization ISO 10993-11	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.	Pass
Systemic Toxicity ISO 10993-11	There was no mortality or evidence of systemic toxicity form the extracts injected into mice. Each test article extract met the requirements of the study.	Pass
Material Mediated Pyrogenicity ISO 10993-11	The total rise of rabbit temperatures during the 3 hour observation period was within acceptable USP requirements. The test article met the requirements for the absence of pyrogens.	Pass

Performance Data

The modifications implemented in ClearPoint Array System were conducted in conformance with the company's design control procedures. Design inputs provided the requirements for the respective product specifications. Design Verification and Validation was performed relative to these specifications and with acceptable results. These tests included verification of physical, performance, and safety requirements, as well as benchtop accuracy testing. The navigational accuracy validation values are presented in the table below.

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

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

Substantial Equivalence

The modifications implemented in ClearPoint Array System were conducted in conformance with the company's design control procedures. Performance testing established the substantial equivalence of the ClearPoint Array System to the predicate ClearPoint System, including design verification testing.

The ClearPoint Array System has the same intended use and similar indications for use, technological characteristics and principles of operation as the predicate ClearPoint System. The minor differences in the workflow and usability do not raise new and different questions of safety and effectiveness.

Conclusions

The ClearPoint Array System has the same intended use and similar indications for use, technological characteristics and principles of operation as the predicate ClearPoint System. The differences between the ClearPoint Array System and the predicate raise no new issues of safety and effectiveness. Thus, the ClearPoint Array System is substantially equivalent to the previously cleared ClearPoint System.