October 20, 2017

MRI Interventions, Inc.
% John Smith, MD JD
Partner
Hogan Lovells US LLP
555 Thirteenth St. NW
Washington, District of Columbia 20004

Re: K171257
Trade/Device Name: ClearPoint System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: ORR, HAW
Dated: September 21, 2017
Received: September 21, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171257

Device Name
ClearPoint System

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. The user should consult the "Navigational Accuracy" section of the User's Guide to assess if the accuracy of the system is suitable for their needs.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

MRI Intervention, Inc.'s ClearPoint Device

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

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Phone: 202-637-5600
Fax: 202-637-5910
Contact Person: John J. Smith, M.D., J.D.

Date Prepared: September 21, 2017

Name of Device and Name/Address of Sponsor

ClearPoint System™

MRI Interventions, Inc.
5 Musick
Irvine, CA 92618

Common or Usual Name:

Neurological Stereotaxic Instrument

Classification

21 C.F.R. §882.4560

Product Code

ORR, HAW

Predicate Device

MRI Interventions, Inc. ClearPoint System (K160434)

Intended Use / 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 and MR Conditional implants and devices. The user should consult the "Navigational Accuracy" section of the User's Guide to assess if the accuracy of the system is suitable for their needs.

Technological Characteristics

The ClearPoint System is comprised of a workstation laptop with workstation software, the SMARTGrid™ MRI-Guided Planning Grid (previously cleared under K100836), the SMARTFrame™ MRI-Guided Trajectory Frame (K100836), the SMARTFrame™ Accessory Kit (K100836) and the SMARTFrame™ Thumbwheel Extension.

The SMARTGrid and associated Marking Tool are designed to assist the physician to precisely position the burr hole as called out in the trajectory planning software. The SMARTFrame is an adjustable trajectory frame 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 allow for trajectory feedback when the physician views the MRI images, makes changes, and confirms with subsequent MR images.

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) that meet the physician's desired imaging quality. MRI Interventions 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 ClearPoint System are the SMARTFrame and Accessories. They are all single use devices that are provided sterile. They include the following:

1. SMARTGrid Pack (interacts with the Software to determine the desired location of the burr hole)
    a. Marking Grid
    b. Marking Tool
2. SMARTFrame Pack
    a. SMARTFrame (adjustable trajectory frame (“ATF”) to guide and hold the neurosurgical tools, includes fiducials, Targeting Cannula, & titanium screws)
    b. Centering Device
    c. Dock
    d. Device Lock (2 different diameters)
    e. Screwdriver
3. Rescue Screws (Extra Titanium Screws)
4. Thumbwheel Extension

5. Accessory Pack
    a. Peel away sheath
    b. Stylet
    c. Lancet
    d. Depth Stop
    e. Ruler
6. Scalp Mount Base
7. Guide Tube and Device Guide Packs (Guide Cannulas)

Each of the above packs is sold separately. Each is intended to be used with the ClearPoint Workstation. 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 (K122456/K151536)
- MRI Neuro Procedure Drape, with Marker Pen and Cover (K091343)
- SmartFrame MR Fiducial (510(k)-exempt Accessory)

The primary purpose of this 510(k) notice is to expand the indications of the device to explicitly include use with the positioning of deep brain stimulator ("DBS") leads. In addition, since the ClearPoint System's last clearance (K160434), an additional locking slot below the top slot in the SmartFrame XG Targeting Cannula ("TC") Support has been added to allow users to retract the TC while the removable support cap is in place. There are now three total locking slots on the TC Support. The software has also been updated to version 1.6.2.

The table below presents a detailed comparison of the technological characteristics of the ClearPoint System and those of the predicate device.

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

	ClearPoint System (Predicate) K160434	**ClearPoint System (Subject)**
Classification	21 CFR 882.4560	21 CFR 882.4560
Product Code	ORR, HAW	ORR, HAW
Intended Use	The ClearPoint System is intended to provide stereotactic guidance 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. 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 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. The user should consult the "Navigational Accuracy" section of the User's Guide to assess if the accuracy of the system is suitable for their needs.

	ClearPoint System (Predicate) K160434	**ClearPoint System (Subject)**
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, Scalp Mount Base, 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, Scalp Mount Base, 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 ID	0.0938, 0.141, 0.191, 0.250”	0.0938, 0.141, 0.191, 0.250”
Guide Tube/ Device Guide / Drill Guide Material	Ultem	Ultem
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	1.6	1.6.2

Performance Data

Literature and registry data demonstrating that the ClearPoint System accurately positions DBS leads in more than 500 patients demonstrates safe and effective use for the new indications. The registry data included data from 35 institutions currently using the ClearPoint System in practice. Accuracy placement data were available on 1,259 procedures, 828 of which were for DBS lead placement.

Results from the company's bench accuracy tests demonstrated that the mean error across device configurations was below 1mm, with the highest standard deviation being 0.45mm and the highest 99% confidence limit being 1.52mm. Angular errors were all below 1°, with the highest standard deviation being 0.55° and the highest 99% confidence limit being 1.40°. These observed values are all below the 2mm and 2° accuracy limits for a stereotaxic device intended for general neurological use.

Substantial Equivalence

The ClearPoint System is as safe and effective as the predicate ClearPoint System (K160434). The ClearPoint System has the same intended use and similar indications, technological characteristics, and principles of operation as the predicate device. Thus the ClearPoint System that is the subject of this submission is substantially equivalent to the previously cleared ClearPoint System.