



November 2, 2018

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

Re: K181195
Trade/Device Name: ClearPoint System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ORR, HAW
Dated: October 5, 2018
Received: October 5, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -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

Indications for Use

510(k) Number (if known)

K181195

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.

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
MRI Intervention, Inc.'s ClearPoint Device

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

Hogan Lovells, US LLP
555 Thirteenth Street, NW
Washington, DC 20004
Phone: 202-637-5600
Fax: 202-637-5910

Contact Person: John J. Smith, M.D., J.D.

Date Prepared: October 5, 2018

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 (K171257)

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.

Device Description

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 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. 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 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
- Camera Fiberscope Accessory Kit

Purpose of 510(k)

The primary purpose of this 510(k) is to modify the ClearPoint System software to version 2.0 by (1) changing the underlying software visualization toolkit used to display reformatted and three-dimensional image renderings; (2) introducing the ability to provide three-dimensional model renderings of the MRI Interventions SMARTGrid and SMARTFrame disposable hardware in combination with 3D volumetric renderings of images that are loaded into the software; (3) changing the DICOM toolkit used to receive images from the MR scanner and loading images from media; (4) adding the ability to fuse/register images together that were not acquired in the same frame of reference; (5) introducing the ability to define three-dimensional volumes of interest within image sets that are loaded into the software; and (6) modifying the software workflow to include new software features and make the existing workflow outlined in the predicate device more flexible.

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

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

	ClearPoint System (Predicate): K171257	ClearPoint System (Subject)
Classification	21 C.F.R. § 882.4560	21 C.F.R. § 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, 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 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 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	1.6.2	2.0

Performance Data

The company performed verification testing for all software changes in the ClearPoint 2.0 software release. Specifically, the following tests were performed to support this 510(k) notice:

Test	Test Method Summary	Results
Integrated System Test	This test utilized a live scanner connection to verify correct interoperation with scanner and disposable hardware kit.	Pass. The design has been verified to satisfy all acceptance criteria. All functional requirements necessitating interfacing with a live MR scanner were satisfied and validated using the software. Nine device placements were evaluated and had accuracy of 1.0 mm or less.
Regression Test	This test used data from the predicate device and included head-to-head comparison with output from the predicate device to support the claim of substantive equivalence.	Pass. The design has been verified to satisfy all acceptance criteria. The following underlying system components still produce output that is consistent with the previously released software version: image display/visualization, image transfer, network communication verification, segmentation library output, scan plane parameter computations, hardware adjustment computations and low-level math utilities.
Verification test	This test used data from the predicate device to execute all areas of functionality of the workstation.	Pass. The design has been verified to satisfy all acceptance criteria. All functional areas within the software behaved as described in the requirements.
Automated UI test	This is an automated test that simulates user input to the ClearPoint software to test functionality that is otherwise difficult or time-consuming to execute as a manual test.	Pass. The design has been verified to satisfy all acceptance criteria. The ClearPoint 2.0 Software has passed the Automated UI test protocol.

The ClearPoint System hardware is identical to that of the predicate; no additional tests for biocompatibility or sterility were provided in support of this 510(k) notice. Biocompatibility data in accordance with ISO 10993 and Sterilization Validation using the overkill method of ISO 11135-1:2007 utilizing the half cycle method was provided in support of the predicate device.

Conclusions

The ClearPoint System is as safe and effective as the predicate ClearPoint System. The ClearPoint System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the ClearPoint System and its predicate devices raise no new issues of safety or effectiveness. Thus, the ClearPoint System is substantially equivalent.