



Food and Drug Administration
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March 24, 2016

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

Re: K160434
Trade/Device Name: ClearPoint System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW, ORR
Dated: February 16, 2016
Received: February 16, 2016

Dear Dr. John Smith:

This letter corrects our substantially equivalent letter of March 17, 2016.

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 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 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 yours,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known)

K160434

Device Name

ClearPoint System

Indications for Use (Describe)

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the MRII ClearPoint System.

1. Company Making the Submission:

Name of Owner:	MRI Interventions, Inc.
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Contact:	Pete Piferi
E-mail:	ppiferi@mriinterventions.com
Date Prepared:	March 15, 2016

2. Device Name:

Common Name:	Neurological Stereotaxic Instrument
Proprietary Name:	ClearPoint System
Classification Name:	Stereotaxic Instrument
Regulatory Class:	II
Regulation Number:	21 C.F.R. § 882.4560
Product Code:	HAW, ORR

3. Predicate Device:

MRII ClearPoint System, K142505

4. 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™ Hand Controller.

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) that meet the physician's desired imaging quality. MRI Interventions also supplies an optional head fixation frame and imaging coil(s) 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:

3. SMARTGrid Pack (interacts with the software to determine the desired location of the burr hole)
 - a. Marking Grid
 - b. Marking Tool
4. SMARTFrame Pack (SMARTFrame or SMARTFrame XG)
 - a. SMARTFrame (“ATF”) with Base
 - b. Centering Tool
 - c. Wharen Centering Guide
 - d. Dock
 - e. Device Lock (2 different diameters)
 - f. Screwdriver
 - g. Roll Lock Screw and Washer
5. Rescue Screws (Extra Titanium Screws)
6. Hand Controller (for use with the ATF) and Thumbwheel Extension
7. Accessory Pack
 - a. Peel-away Sheath
 - b. Stylet
 - c. Lancet
 - d. Depth Stop
 - e. Ruler
8. Scalp Mount Base
9. Guide Tube and Device Guide Packs (Guide Cannulas)
10. SmartTip MRI Hand Drill and Drill Bit Kit
11. SmartTwist MRII Hand Drill and 4.5mm/6.0mm Drill Guide
12. MRI Neuro Procedure Drape, with Marker Pen and Cover
13. MR Camera Fiberscope Accessory Kit
14. SmartFrame MR Fiducial

Each of the above packs is sold separately. Each is intended to be used with the ClearPoint Workstation.

5. Indications for 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.

6. Comparison of the Technological Characteristics of the Device with the Predicate Device:

Modifications to the predicate ClearPoint System are as follows:

- a) Addition of 4.5mm and 6.0mm Drill Guides that are compatible with the SmartFrame XG and can be used in place of the Targeting Cannula to facilitate the use of the cleared SmartTwist MRII Hand Drill (K151536) with the SmartFrame XG.

- b) Addition of the Wharen Centering Guide, an optional accessory designed to make the cleared Centering Tool (K100836) easier to use with the Scalp Mount Base. The use of this accessory is not required for proper use of the ClearPoint System, does not materially alter the clinical work flow, and does not change the intended use of the device. It can hold the Centering Tool in place and eliminate potential scalp movement during a) removing the lower pad of the Marking Grid, and b) during mounting of the Scalp Mount Base. Eliminating scalp movement during these steps will help ensure an accurate alignment of the SmartFrame to the entry point.

	ClearPoint System K142505	ClearPoint System Modified
Classification	21 CFR 882.4560	21 CFR 882.4560
Product Code	HAW, ORR	HAW, ORR
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. 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, Scalp Mount Base, Screws, Stand-Off Pins, Screwdriver, Centering Tool, 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	Not included	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"	0.0938, 0.141, 0.191, 0.250"
Guide Tube /	Ultem	Ultem

	ClearPoint System K142505	ClearPoint System Modified
Device Guide / Drill Guide Material		
Packaging	Sterile, Sealed Tray, Inside Sterile Tyvek Pouch	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	1.5	1.6

7. Performance Data:

Bench and phantom testing confirmed that the Wharen Centering Guide can be used to help hold the Centering Tool in place and maintain the selected entry point. Design verification was performed on the 4.5mm and 6.0mm Drill Guides with acceptable results. The tests demonstrated that the modified ClearPoint System functions as intended and is substantially equivalent to the legally marketed device.

The ClearPoint System complies with the following recognized consensus standards:

- AAMI/ANSI/ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing.
- ANSI/AAMI/ISO 11135-1 Sterilization of health care - products - Ethylene oxide - Part 1: Requirements for development, validation, and routine control of sterilization process for medical devices.

8. Conclusions:

The modifications to the ClearPoint System were made in conformance with the company's design control procedures and the performance testing performed for the predicate ClearPoint System (K142505). The modified ClearPoint System has the same intended use and indications for use and similar technologies characteristics and principles of operation as the predicate ClearPoint System. The minor technological differences between the modified ClearPoint System and its predicate ClearPoint System raise no new issues of safety and effectiveness. Thus, the modifications are substantially equivalent to the previously cleared ClearPoint System.