



February 13, 2020

MRI Interventions, Inc
% John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth St. N.W.
Washington, District of Columbia 20004

Re: K200079

Trade/Device Name: ClearPoint System and Accessories
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 14, 2020
Received: January 14, 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,

Matthew Krueger, M.S.E.
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

Indications for Use

510(k) Number (if known)

K200079

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 Interventions ClearPoint System

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

Hogan Lovells, US LLP
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Phone: 202-637-5600
Fax: 202-637-5910

Contact Person: John J. Smith, M.D., J.D. Date Prepared: January 14, 2020

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: HAW

Predicate Device: ClearPoint System and Accessories (K181195)

Purpose of the Special 510(k) notice.

The ClearPoint System and Accessories is a modification to the predicate ClearPoint System and Accessories (K181195).

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 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. Thumbwheel Extension
4. Accessory Kit
 - a. Peel-away Sheath (2)
 - b. Stylet
 - c. Lancet
 - d. Depth Stop (2)
 - e. Ruler
5. Scalp Mount Base
6. Guide Tubes and Device Guide Packs (Guide Cannulas).

MRI Interventions Devices that can also be used with ClearPoint

1. SmartTip Drill Bit Kit
2. MRI Hand Drill
3. SmartFrame MR Fiducial
4. MRI Neuro Procedure Drape
5. Camera Fiberscope Accessory Kit
6. ClearPoint Pursuit

Technological Characteristics

Modifications of the predicate MRII ClearPoint System are:

1. There are two new Accessory Kits that are being made available: A 5 Fr Accessory Kit, and a 7 Fr Accessory Kit. The new Accessory Kits have slightly larger-sized Stylets, Lancets, and Peel Away Sheaths than the current Accessory Kit. The materials used in the new Accessory Kit components are identical to the predicate device components. There are new Device Guides with slightly larger ID's that are to be used with the corresponding larger Peel Away Sheaths. There are new Device Locks and Docks with slightly larger ID's that are to be used with the corresponding larger Peel Away Sheaths.

- i. The new 5 Fr Accessory Kit has a 0.067" OD Stylet, a 0.067" OD Lancet, two 0.100" ID Depth Stops, a Ruler, and two 5 Fr ID (0.070" ID) Peel Away Sheaths.
 - ii. The new 7 Fr Accessory Kit has a 0.097" OD Stylet, a 0.097" OD Lancet, two 0.100" ID Depth Stops, a nylon Ruler, and two 7 Fr ID (0.098" ID) Peel Away Sheaths.
2. There are two new Device Guides for use with the new Accessory Kit Peel-Away Sheath sizes. The 2.5-mm (0.099") ID Device Guide is available to be used with the 5-Fr ID Peel Away Sheath. The 3.2-mm (0.128") ID Device Guide is available to be used with the 7-Fr ID Peel Away Sheath.
3. There are two new SmartFrame XG Kits: A 5 Fr Kit and a 7 Fr Kit. The new kits contain Device Locks and Docks to be used with the 5 Fr or 7 Fr Accessory Kits. There is a 0.078" ID Device Lock for use with the 5 Fr Stylet, and a 0.100" ID Device Lock for use with the 7 Fr Stylet. There is a 0.104" ID Dock for use with the 5 Fr Peel Away Sheath, and a 0.140" ID Dock for use with the 7 Fr Peel Away Sheath.

All of the technological characteristics are identical to the predicate ClearPoint System and Accessories. Materials, form, function, interface with other components, and user interface are identical.

Performance Data

The modifications of the ClearPoint System were conducted in conformance with the company's design control procedures. Design inputs provided the requirements for the respective product specifications. Design Verification was performed relative to these specifications with acceptable results. These tests included verification of physical, performance, and safety requirements, as well as benchtop accuracy testing. Risk analysis was performed with mitigation of all identified risks to acceptable levels. The tests and risk analysis demonstrated that the modified ClearPoint system functions as intended and is substantially equivalent to the legally marketed ClearPoint System.

Substantial Equivalence

The modifications to the ClearPoint System and accessories were made in conformance with the company's design control procedures. Performance testing established the substantial equivalence of the modified ClearPoint System and accessories to the predicate ClearPoint System and accessories, including design verification testing.

The ClearPoint System and accessories has the same intended use and indications for use and the same technological characteristics and principles of operation as the predicate ClearPoint System and accessories. The minor dimensional differences between the ClearPoint System and accessories and its predicate raise no new issues of safety and effectiveness. Thus, the modifications are substantially equivalent to the previously cleared ClearPoint System and accessories.

Conclusions

The ClearPoint System and accessories has the same intended use and indications for use and the same technological characteristics and principles of operation as the predicate ClearPoint System and accessories. The minor dimensional differences between the ClearPoint System and accessories and its predicate raise no new issues of safety and effectiveness. Thus, the modified devices are substantially equivalent to the previously cleared ClearPoint System and accessories.