June 21, 2019

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

Re: K191400
Trade/Device Name: Voyager Trajectory Array Guide (V-TAG)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: May 24, 2019
Received: May 24, 2019

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 Statement

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 on last page

510(k) Number *(if known)*

K191400

Device Name
V-TAG

Indications for Use *(Describe)*

The V-TAG is intended to assist with stereotactic guidance, placement, and fixation for the operation of surgical instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and perioperative MR imaging. These procedures include laser coagulation, biopsies, catheter placement and electrode placement procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA)
Staff PRAStaff@fda.hhs.gov

"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."

510(k) SUMMARY

MRI Interventions V-TAG

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: May 24, 2019

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: Voyager Trajectory Array Guide (V-TAG) (K180854)

Purpose of the Special 510(k) notice.

The V-TAG is a modification to the predicate V-TAG (K180854).

Intended Use

The V-TAG is intended to assist with stereotactic guidance, placement, and fixation for the operation of surgical instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and perioperative MR imaging. These procedures include laser coagulation, biopsies, catheter placement and electrode placement procedures.

Device Description

The V-TAG™ device is a single-use, skull-mounted, rigid trajectory array guide used in stereotactic surgical procedures. The V-TAG can be manipulated to provide a wide range of

surgical trajectories into the head. An image-guided neuronavigational system loaded with a stereotactic surgical plan is used to align the V-TAG to the planned trajectory; once aligned, the V-TAG is securely locked to provide a stable instrument guide. After positioning of the V-TAG, magnetic resonance imaging (MRI) is used to confirm alignment with the planned trajectory. Adjustment of the V-TAG may be performed in the MRI scanner to refine or change the trajectory based on updated intraoperative imaging. Intracranial placement of a neurosurgical device or surgical instrument using the V-TAG device is only to be performed after MRI confirmation of the trajectory.

Technological Characteristics

The V-TAG device is a single use, MR compatible, sterile medical device consisting of a Base that is temporarily attached to the skull with four bone screws during the surgical procedure , a trajectory Guide containing seven channels to guide the insertion of 14-gauge neurosurgical devices or instruments, a Handle to assist with alignment using standard stereotactic surgical procedures, a Center Adaptor to identify the center trajectory of the Guide, an Imaging Cartridge to be filled with an FDA approved diluted gadolinium-based contrast agent (not included, no patient contact), and a Reducer for use with 16-gauge neurosurgical devices or instruments.

Performance Data

Accuracy testing was performed using the modified alignment technique for the V-TAG. For each trial, the beginning alignment was intentionally set to an error greater than 10mm. Alignment was then performed using rapid-refresh scanner sequences to manually align the center lumen of the V-TAG to the target. Projected errors were then calculated. If the projected error was more than 4mm, alignment was performed again. All placements met the acceptance criteria of X, Y, Z errors ≤2.0mm and angular error of ≤2°.

Substantial Equivalence

The modified V-TAG has the same intended use and similar indications, principles of operation, and technological characteristics as its predicate. The minor differences in the V-TAG's instructions for use do not raise any new questions of safety or effectiveness. Performance data demonstrates that the V-TAG is as safe and effective as its predicate. Thus, the V-TAG is substantially equivalent to its predicate device.

Conclusions

The V-TAG has the exact same intended use, indications for use, and substantially similar technological characteristics as the predicate. The purpose of this Special 510(k) notice was to modify the instructions for use of the device to allow for trajectory adjustments in the MRI scanner based on interoperative imaging. Accuracy testing provided in this submission demonstrate that the modified V-TAG accuracy is equivalent to that of the predicate device. Thus, the V-TAG is substantially equivalent.