November 15, 2019

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

Re: K191701
  Trade/Device Name: Arcus Head Fixation Frame
  Regulation Number: 21 CFR 882.4460
  Regulation Name: Neurosurgical Head Holder (Skull Clamp)
  Regulatory Class: Class II
  Product Code: HBL
  Dated: October 16, 2019
  Received: October 16, 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.


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 C. Krueger -S

Matthew Krueger
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
510(k) Number (if known)

K191701

Device Name

Arcus Head Fixation Frame

Indications for Use (Describe)

The Arcus Head Fixation Frame is intended for use as a device to clamp and hold the patient’s head in a particular position for procedures requiring Magnetic Resonance Imaging (MRI) of the brain structure and targets.

Type of Use (Select one or both, as applicable)

X 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.

*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.”
MRI Interventions, Inc.’s Arcus Head Fixation Frame

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

MRI Interventions, Inc.
5 Musick
Irvine, CA 92618
Phone: 949-900-6833
Fax: 949-900-6834
Contact Person: Peter Piferi, C.O.O
Date Prepared: October 16, 2019

Name of Device and Name/Address of Sponsor
Arcus Head Fixation Frame
MRI Interventions, Inc.
5 Musick
Irvine, CA 92618

Common or Usual Name
Neurosurgical head holder (skull clamp)

Classification
21 C.F.R. § 882.4460

Product Code
HBL

Predicate Device
SurgiVision, Inc.’s Head Fixation Arc and Table Base (K091439)

Intended Use / Indications for Use
The Arcus Head Fixation Frame is intended for use as a device to clamp and hold the patient’s head in a particular position for procedures requiring Magnetic Resonance Imaging (MRI) of the brain structure and targets.

Technological Characteristics
The technical modes of action and technical principles are materially the same as the predicate device, including: head fixation frame (HFF) design and construction, materials being functionally similar in all cases (identical in several aspects), and relying upon the same principles of head stabilization/immobilization including the securing/clamping of the frame to the scanner table and the physician locating and securing the patient’s skull using hand tightened skull pins. The primary design differences are as follow:

- The Arcus HFF allows removal of the Ring (that secures the patient’s skull in the skull pins) so the physician can pin the patient away from the rest of the HFF with good visibility to
complete the pinning. This allows the physician to pin a patient while they are in a supine position and then move them to the scanner table to position the patient in the prone position and secure the Ring in the Base of the HFF.

- The Arcus HFF provides vertical, rotational, and angular adjustment of the Ring once in the Base to assist the positioning of patients that might have neck or spinal abnormalities that hinder normal head fixation. The Ring is then secured to the Base.

- The Arcus HFF has (6) Posts that can be mounted onto the Ring to hold 4 different lengths of Fixation Screws, providing the physician flexibility when locating the Skull Pins (that are inserted into the ends of the fixation screws) on the patient’s skull. The Arcus HFF is secured to the scanner table in the same manner as the predicate device, using features on the scanner table that normally are used to attach straps for securing the patient.

The Arcus HFF is designed for use with Siemens Avanto, Espree, Symphony, Sonata, Tria, and Verio MRI Scanners.

The Arcus HFF is re-usable and is sold non-sterile. The device does not require sterilization.

The Arcus HFF is MR Conditional, as it contains brass inserts and titanium pin tips which will be present during MRI scanning. Only the Titanium Pin tips contact the patient. The Pin Tips are an accessory to the device system and are not packaged with the device. The Sterile Titanium Pin Tips are marketed by Pro Med Instruments, Inc. (K001808).

**Performance Data**

Bench testing was performed to verify the Arcus HFF secures the patient's skull to the HFF. The method of securing HFF to the scanner table is unchanged from the predicate device and did not require repetition of testing. Additional testing to confirm MR safety regarding heating, image distortion, and magnetic attraction were completed. Testing confirmed the Arcus HFF met the Product Specification Requirements.

The tests demonstrated that the Arcus HFF functions as intended and is substantially equivalent to the legally marketed predicate.

The following recognized consensus standards were utilized in the development of the Arcus HFF:

- ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
**Substantial Equivalence**

The Head Fixation Arc and Table Base and the Arcus Head Fixation Frame have identical intended use and indications for use. As shown in the below table, the technological characteristics of the Arcus HFF are substantially similar to those of the predicate device. Any minor differences do not raise new questions of safety or effectiveness.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Arcus Head Fixation Frame (candidate)</th>
<th>Head Fixation Arc and Table Base - K091439 (predicate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification Regulation</td>
<td>21 C.F.R. § 882.4460</td>
<td>21 C.F.R. § 882.4460</td>
</tr>
<tr>
<td>Product Code</td>
<td>HBL</td>
<td>HBL</td>
</tr>
<tr>
<td>Prescription device</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Composition</td>
<td>Garolite G-10</td>
<td>Fiberglass</td>
</tr>
<tr>
<td></td>
<td>Same as Predicate</td>
<td>Delrin</td>
</tr>
<tr>
<td></td>
<td>Same as Predicate</td>
<td>PEEK</td>
</tr>
<tr>
<td></td>
<td>---------</td>
<td>Ceramic</td>
</tr>
<tr>
<td>Brass (threaded inserts)</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>Titanium (fasteners)</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>Shape of Skull Clamp</td>
<td>Ring</td>
<td>Fixation Arc</td>
</tr>
<tr>
<td></td>
<td>U-shaped (partial ring) or Circular (full ring)</td>
<td>U-Shaped Arc</td>
</tr>
<tr>
<td>Scanner Table attachment method</td>
<td>Same as predicate</td>
<td></td>
</tr>
<tr>
<td>Types of scanner tables intended to fit.</td>
<td>Same as predicate</td>
<td>The Table Base (shown) is designed to mate with Siemens Avanto MRI. Minor modifications of the table Base would allow the mating to other MRI systems.</td>
</tr>
<tr>
<td>Skull Clamp adjustability</td>
<td>Removable Ring.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cradle secures the Ring.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cradle adjusts in “Y” direction.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cradle top adjusts in the “Z” direction.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Permanently attached to the table clamps.</td>
<td></td>
</tr>
<tr>
<td>Fixation Screw locating</td>
<td>Screw locations have 360° positioning. Up to 6 locations can be used in the 13 positions on the ring.</td>
<td>4 Screw locations are fixed.</td>
</tr>
<tr>
<td>Head Fixation Screws (hand tightened)</td>
<td>Same as Predicate</td>
<td>Yes</td>
</tr>
<tr>
<td>***Sterile Titanium Pin tips (needed for the procedure but not provided with the product)</td>
<td>Same as Predicate</td>
<td>Yes (mfg. by Pro Med Instruments – DORO)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Arcus Head Fixation Frame (candidate)</td>
<td>Head Fixation Arc and Table Base - K091439 (predicate)</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---------------------------------------</td>
<td>---------------------------------------------------------</td>
</tr>
<tr>
<td>Sold Sterile</td>
<td>Same as Predicate</td>
<td>No</td>
</tr>
<tr>
<td>Requires Sterilization</td>
<td>Same as Predicate</td>
<td>No</td>
</tr>
<tr>
<td>before Use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRI Safe</td>
<td>*MR Conditional</td>
<td>**MR Conditional</td>
</tr>
</tbody>
</table>

* Considered conditional due to the use of the titanium pin tips.
** Considered conditional due to the presence of brass inserts and the use of the titanium pin tips.
*** These are not provided with the product but are obtained by the hospitals from either DORO or MRII (as a distributor). They are sterile disposables. They are listed here because they are necessary for the use of the HFF.

**Conclusions**
The Arcus HFF is as safe and effective as the Head Fixation Arc and Table Base. The Arcus HFF has the same intended use and indications for use, as well as substantially similar technological characteristics as its predicate device. The minor technological differences between the Arcus HFF and its predicate device raise no new issues of safety or effectiveness. Thus, the Arcus HFF is substantially equivalent.