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

November 20, 2018

Re: K181731
Trade/Device Name: MR Compatible Aspiration Kit
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: October 24, 2018
Received: October 24, 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,

For John Marler -S

Digitally signed by John Marler -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John Marler -S, 0.9.2342.19200300.100.1.1=0010167268
Date: 2018.11.20 15:47:25 -05'00'

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181731

Device Name
MR Compatible Aspiration System

Indications for Use *(Describe)*
The MR Compatible Aspiration System is used for controlled aspiration of blood, clotted blood, cystic components of tumors, abscess, colloid cysts, and cerebrospinal fluid using a manual syringe during surgery of the Ventricle System or Cerebrum.

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, Inc.'s MR Compatible Aspiration Kit

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: November 20, 2018

Name of Device and Name/Address of Sponsor

MR Compatible Aspiration Kit ("MCA Kit")

MRI Interventions, Inc.
5 Musick
Irvine, CA 92618

Common or Usual Name:
Neurological Endoscope

Classification
21 C.F.R. § 882.1480

Product Code
GWG

Predicate Device
Penumbra Apollo System (K152699)

Intended Use / Indications for Use
The MR Compatible Aspiration System is used for controlled aspiration of blood, clotted blood, cystic components of tumors, abscess, colloid cysts, and cerebrospinal fluid using a manual syringe during surgery of the Ventricle System or Cerebrum.

Device Description
The MCA Kit is an accessory to the cleared ClearPoint System (K171257). The MCA Kit consists of a MCA device guide, guide sheath, stylet, depth stops, cannula (with attached tube) and adapter. The MCA Kit is designed to aid a physician in the removal of specific tissue or fluid types from the brain during image guided surgery. It is MR safe, as all materials are non-metallic. The MCA Kit is comprised of single use only, sterile-packaged disposable components that are packaged together.

The MCA Kit is available in the following configurations:

Kit Configuration	**Guide Sheath Size (Outer Diameter)**	**Cannula Size (Outer Diameter)**	**Cannula Length (Approximate)**	**Maximum Target Depth (mm)**
15 Fr – Long	15 Fr	12 Fr	12.2" / 31 cm	120
17 Fr – Long	17 Fr	14 Fr	12.2" / 31 cm	120
19 Fr – Long	19 Fr	16 Fr	12.2" / 31 cm	120
15 Fr – Short	15 Fr	12 Fr	9.4" / 24 cm	70
17 Fr – Short	17 Fr	14 Fr	9.4" / 24 cm	70
19 Fr – Short	19 Fr	16 Fr	9.4" / 24 cm	70

Performance Data

Bench testing was performed to verify the MCA Kit's compatibility with the ClearPoint System, accuracy, and substantial equivalence to the predicate aspiration device.

Test	Test Method Summary	Results
Accuracy Testing	The company used the same ground truth procedure and test methods that were used in the accuracy testing provided in support of K142505 and K171257 for the ClearPoint System. The test set-up utilized only the scalp mount bases and SmartFrame XG, since the MCA Kit must be used with the SmartFrame XG to allow device guide insertion, and the scalp mount base is the most likely configuration to be used clinically. Placements were performed using the 12 Fr x 30 cm and 16 Fr x 30 cm MCA Kits, which represent the smallest and largest OD sizes; accordingly, the test results support the performance of all sizes of the MCA kit. Target depth was 125 mm from the base-mounting surface for all placements.	Results from the company's bench accuracy tests demonstrated that the mean error was below 1.0mm, with the highest standard deviation being 0.75mm in the X direction and highest 99% upper confidence limit of 1.48mm in the X direction. The mean angular error was below 1°, with a standard deviation of 0.34° and 99% upper confidence limit of 0.72°. These values are below the 2mm and 2° accuracy limits for a stereotaxic device intended for general neurological use.
MCA-Kit Device Guide– SmartFrame XG Compatibility	Performance testing was completed to verify that the device guide and SmartFrame XG are compatible per pre-defined acceptance criteria. Testing included insertion and retention of the Device Guide and Adapter to the SmartFrame under tensile and torque loading, stability of the Guide Sheath-Stylet and Guide Sheath-Cannula under lateral loading when inserted in the SmartFrame, and accuracy with the SmartFrame.	All acceptance criteria were met to demonstrate that the MCA Kit components are compatible with the cleared ClearPoint System SmartFrame XG.

Flow and Leak Testing	Testing was conducted to confirm that the device could aspirate at least 10cc of various materials simulating blood, clotted blood, cystic components of tumors, abcesses, colloid cysts, and cerebrospinal fluid without leaking or collapsing and at an acceptable flow rate.	The tests demonstrated that the MCA Kit functions as intended and is substantially equivalent to the legally marketed predicate
Aspiration Test	Testing was performed to confirm the device remains operable for a limited period of time at 29.0 inHg for the MCA Kit Cannulas Twelve Fr. and 16 Fr. Cannulas that have undergone worst-case conditioning were used for this test. Plugged cannulas were evaluated under high vacuum generated by a pump to create worst-case conditions. The change in device inner diameter (I.D.) was measured to confirm that the device's integrity was maintained during the aspiration. The device was also verified to remain undamaged after exposure to the conditions.	All Cannulas tested were able to withstand collapsing, leaking, or failing in any other manner when experiencing a minimum aspiration pressure of 29.0 inHg. The measured change in the Rigid section I.D. of the Cannulas was 0.0% for the 12 Fr., and 0.8% for the 16 Fr. The flexible Tubing had a measured change in I.D. of 1.3% for the 12 Fr. and 2.9% for the 16 Fr. Cannulas. The device can operate for a limited period of time at an aspiration pressure of 29.0 inHg without failing.

The MCA Kit complies with the following recognized consensus standards:

- ANSI/AAMI/ISO 11137-2: Sterilization of Health Care Products – Radiation – Establishing the sterilization dose – Method VDmax
- ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ASTM F2096-11: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM D4196-16: Standard Test Method for Confirming the Sterility of Membrane Filters
- ASTM F1980-16: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Substantial Equivalence

The Apollo System and MR Compatible Aspiration Kit have substantially similar intended use and indications for use. The table below presents a comparison of the technological characteristics of the MR Compatible Aspiration Kit and those of the predicate device.

	Apollo System K152699	**MR Compatible Aspiration Kit**
Wand (Cannula) O.D / I.D.	1 size: Body = .083" / .069" Distal Tip = .072" / .059"	3 sizes: 12F = .158" / .138" 14F = .183" / .163" 16F = .208" / .190"

	Apollo System **K152699**	**MR Compatible Aspiration Kit**
Usable Length	27.2 cm	Maximum insertion length is 12.5cm due to height of SmartFrame
Basic Operating Principle	AC power is converted from the generator into vibrational energy to the distal tip of the wand, which removes tissue and/or fluids through and aspiration lumen	Manual actuation of the syringe plunger provides vacuum to the distal tip of the cannula which removes tissue and/or fluids through the aspiration lumen
Aspiration	0–29 in.HG	0–29 in.HG
Disposable Components	• Wand • Collection Canister, filter and pump-canister tubing • Irrigation Tubing	• Cannula w/ tubing • Stylet • Guide Sheath • Depth Stop • SmartFrame Adapter and Device Guide
Power Requirements	100–115V (60Hz), 100V (50Hz)	N/A Manual Control
Navigation	Image Guidance	Image Guidance

Conclusion

The MCA Kit and Apollo System have substantially similar intended use and indications for use, as well as similar technological characteristics. The minor technological differences in the MCA Kit compared to the Apollo System do not raise new questions of safety or effectiveness. The MCA Kit's accuracy, compatibility with the ClearPoint System SmartFrame XG, flow, leak, and aspiration testing further confirm that the device performs as intended and is substantially equivalent to the legally marketed predicate.