March 2, 2022

Mizuho America, Inc.
Richard Chadwick
Senior Manager, Operations and QA
30057 Ahern Avenue
Union City, California 94587

Re: K211183
Trade/Device Name: Sugita AVM Microclips
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm Clip
Regulatory Class: Class II
Product Code: HCH
Dated: January 25, 2022
Received: January 31, 2022

Dear Richard Chadwick:

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,

Naira Muradyan, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211183

Device Name
Sugita AVM Microclips

Indications for Use *(Describe)*

The Sugita AVM Microclips are designed for occlusion of fragile capillary vessels to stop bleeding from arteriovenous malformations and other analogous venous structures.

Sugita AVM Microclips are not intended as a replacement for bipolar electrocoagulation of smaller vessels nor do they negate the need for immediate post-operative angiography following arteriovenous malformation surgery.

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.

K211183

510(k) SUMMARY

Applicant Information:

Owner Name:	Mizuho America, Inc.
Address:	30057 Ahern Avenue Union City, CA 94587
Phone number:	+1(510) 324-4500
Establishment Registration Number:	1223656
Contact Person:	Richard Chadwick
Date Prepared:	February 28, 2022

Device Information:

Device Classification:	Class II
Trade Name:	Sugita AVM Microclips
Common name:	Aneurysm Clip
Classification name:	Aneurysm Clip
Regulation number:	882.5200
Product Code:	HCH

Predicate Device:

Sugita AVM Microclips (K960037).

Device Modification:

The following changes have been made to the Sugita AVM Microclips:

- The device has been demonstrated to be safe for imaging in both 1.5- Tesla and 3-Tesla MR systems.
- New parameters for steam sterilization are provided for end users.

Device Description:

The Sugita AVM Microclips were cleared by the FDA through 510(k) K960037. The Sugita AVM Microclips are manufactured from Elgiloy, a cobalt-chromium-molybdenum alloy. They are designed for the occlusion of fragile capillary vessels to stop bleeding from arteriovenous malformations and other analogous venous structures. The Sugita AVM Microclips are available in the following sizes: 2mm, 3mm, 4mm and 5mm. Other than the modifications identified above, there have been no other changes to the Sugita AVM Microclips.

Indications for Use:

The Sugita AVM Microclips have the same Indications for Use as the predicate device.

> The Sugita AVM Microclips are designed for occlusion of fragile capillary vessels to stop bleeding from arteriovenous malformations and other analogous venous structures.
>
> Sugita AVM Microclips are not intended as a replacement for bipolar electrocoagulation of smaller vessels nor do they negate the need for immediate post-operative angiography following arteriovenous malformation surgery.

Comparison of Technological Characteristics to the Predicate Device:

Both the Sugita AVM Microclips and the predicate device have the same intended use. Both are intended for occlusion of small vessels in Arteriovenous Malformations (AVM's) and other similar structures.

The materials, design, technological characteristics and operating principles of the current device are unchanged from the predicate cleared through K960037. See the table below.

Substantial equivalence in materials, technological characteristics, and performance of the Sugita AVM Microclips to the predicate device is outlined in the table below:

Product	**Sugita AVM Microclips**	**Sugita AVM Microclips**	**Conclusion**
510(k) number	Subject Device – K211183	K960037	
Manufacturer	Mizuho America, Inc.	Mizuho America, Inc.	
Materials			
	Elgiloy (cobalt-chromium-molybdenum alloy – ASTM F1058)	Elgiloy (cobalt-chromium-molybdenum alloy – ASTM F1058)	**SAME**
Technological Characteristics			
Designed with a predetermined holding force	Holding force of 50 to 70g	Holding force of 50 to 70g	**SAME**
Various Sizes for specific requirements	Four Sizes Available – 2mm, 3mm, 4mm and 5mm	Four Sizes Available – 2mm, 3mm, 4mm and 5mm	**SAME**
Delivery to Surgical Site	Sugita Microclip Applier designed specifically for Sugita AVM Microclips to aid in delivery to surgical site	Microclip Applier designed specifically for Sugita AVM Microclips to aid in delivery to surgical site	**SAME**

Product	Sugita AVM Microclips	Sugita AVM Microclips	Conclusion
510(k) number	Subject Device – K211183	K960037	
Manufacturer	Mizuho America, Inc.	Mizuho America, Inc.	
Steam Sterilized by end user	Cycle Type: Pre-vacuum • Temperature: 132°C • Exposure Time: 4 min. • Drying Time: 20 min. • Temperature: 134°C • Exposure Time: 3 min. • Drying Time: 20 min.	Cycle Type: Pre-vacuum • Temperature: 252°F • Exposure Time: 20 minutes	**Substantially Equivalent**
Performance Testing			
MRI Safety	MR Conditional for Use in Both 1.5T and 3T MR Systems Based on Testing: -Magnetic Field Interactions -MRI Related Heating -MRI Artifact Test	MR Conditional for Use in 1.5T MR Systems	**Substantially Equivalent**

Non-clinical Performance Testing

Performance testing was conducted to demonstrate the safety of the Sugita AVM Microclips for imaging in both 1.5-Tesla and 3-Tesla MR Systems and to provide labeling for MRI safety of the device conforming to ASTM F2503-13 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment* and *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, Guidance for Industry and Food and Drug Administration Staff*, document issued on May 20, 2021.

Additionally, sterilization validation testing was conducted to provide recommended steam sterilization parameters for the device.

Non-clinical Performance Testing Summary

Test	Test Summary	Conclusions
MRI Compatibility Testing – Magnetic Field Interaction (force)	Testing according to ASTM F2052-15 -translational attraction determined to be 14°.	Force no greater than gravitational field.
MRI Compatibility Testing – Magnetic Field Interaction (torque)	Testing according to ASTM F2213-17 – torque showed no movement or alignment.	Magnetically induced torque is not substantial and requires no further evaluation.
MRI Compatibility Testing – MRI Related Heat Testing	Testing according to ASTM F2182-19 – maximum temperature rise of 1.5°C after 15 min. of continuous scan.	Maximum Whole Body Averaged SAR 2-W/Kg for 60 min. continuous RF exposure.

MRI Compatibility Testing – Imaging Artifact Testing	Testing according to ASTM F2119-2013 – image artifact extends approx. 10mm from implant with 3-Tesla gradient echo pulse sequence.	The presence of this implant produces an imaging artifact. Therefore, should carefully select pulse sequence parameters if the implant is located in the area of interest.
MRI Compatibility Testing – Spatial Gradient Magnetic Field Testing	5mm Sugita AVM Microclips were attached to a porcine blood vessel in order to conduct a digital force gauge-based Pull-Test.	Testing supports using a value of 2,000 gauss/cm (20-T/m) for the MRI related labeling of the Sugita AVM Microclips.
Steam Sterilization Validation Testing	Testing according to ISO 17665-1 was performed to validate steam sterilization parameters for the Sugita AVM Microclips using an FDA cleared nonwoven wrap to a sterility assurance level of (SAL) of 10^{-6}.	Validated steam sterilization parameters are provided in the product labeling.

Shelf-life

The Sugita AVM Microclips do not have a shelf life because they are provided non-sterile and are constructed of inert materials. Performance data are not needed to establish maintenance of device performance over the shelf life of the Sugita AVM Microclips because the materials of construction of these products are highly stable metal alloys with a long history of use in surgical implants.

Biocompatibility

The proposed changes do not impact the contact duration or biocompatibility profile of the Sugita AVM Microclips.

Conclusion

The modified Sugita AVM Microclips subject to this submission are substantially equivalent to the predicate, Sugita AVM Microclips, in the following ways: they have the same intended use and Indications for Use, the same technological characteristics and operating principles, and incorporate the same design and materials.

Performance testing has demonstrated that the Sugita AVM Microclips are substantially equivalent to the predicate and are safe for imaging in both 1.5- Tesla and 3-Tesla MR systems. In addition, validated parameters for steam sterilization and cleaning are provided to update the instructions for end users of the device.