June 24, 2022

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

Re: K221524
Trade/Device Name: Sugita AVM Microclip Applier
Regulation Number: 21 CFR 882.4175
Regulation Name: Aneurysm Clip Applier
Regulatory Class: Class II
Product Code: HCI
Dated: May 25, 2022
Received: May 26, 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)*
K221524

Device Name
Sugita AVM Microclip Applier

Indications for Use *(Describe)*

The Sugita AVM Microclip Applier is exclusively designed to place Sugita AVM Microclips during surgical 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)

**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."*

# K221524 510(k) SUMMARY

## Applicant Information:

| | |
|---|---|
| Owner Name: | Mizuho America, Inc. |
| Address: | 30057 Ahern Avenue<br>Union City, CA 94587 |
| Phone number: | +1(510) 324-4500 |
| Establishment Registration Number: | 1223656 |
| Contact Person: | Richard Chadwick |
| Date Prepared: | June 12, 2022 |

## Device Information:

| | |
|---|---|
| Device Classification: | Class II |
| Trade Name: | Sugita AVM Microclip Applier |
| Common name: | Aneurysm Clip Applier |
| Classification name: | Aneurysm Clip Applier |
| Regulation number: | 882.4175 |
| Product Code: | HCI |

## Predicate Device:

Aesculap Slim Clip Applier (K211572).

## Reference Device:

Sugita AVM Microclip (K960037).

## Device Modification:

The following changes have been made to the Sugita AVM Microclip Applier:

- Updated steam sterilization parameters;
- Updated cleaning instructions;
- Product specific Instructions for Use.

## Device Description:

The Sugita AVM Microclip Applier has a spring handle design with a ratchet. The Sugita AVM Microclip Applier serves to open and close the Sugita AVM Microclips. Using the Sugita AVM Microclip Applier, the Sugita AVM Microclips are removed from their packaging and applied, repositioned or removed from the

target tissue. The Sugita AVM Microclip Applier has no function of its own and may only be used in combination with the Sugita AVM Microclips.

The Sugita AVM Microclip Applier has the same design and materials as the clip applier in the K960037. The body of the Sugita AVM Microclip Applier is manufactured from stainless steel and the jaws are manufactured from Elgiloy, a cobalt-chromium-molybdenum alloy.

**Indications for Use:**

The Sugita AVM Microclip Applier is exclusively designed to place Sugita AVM Microclips during surgical procedures.

**Comparison of Technological Characteristics to the Predicate Device:**

The Sugita AVM Microclip Applier and the predicate device have the same intended use for holding and applying intracranial aneurysm clips.

The materials, design, technological characteristics and operating principles of the subject device are unchanged from the reference device (K960037) and are substantially equivalent to the predicate device, Aesculap Slim Clip Applier (K211572).

The comparison of the indications for use, materials and technological characteristics of the Sugita AVM Microclip Applier to the predicate and reference devices is outlined in the table below:

| Product | Sugita AVM Microclip Applier | Sugita AVM Microclip | Aesculap Slim Clip Applier | Conclusion |
|---|---|---|---|---|
| **510(k) number** | Subject Device K221524 | Reference Device K960037 | Predicate Device K211572 | |
| **Manufacturer** | Mizuho America, Inc. | Mizuho America, Inc. | Aesculap, Inc. | |
| **Indications for Use** | The Sugita AVM Microclip Applier is exclusively designed to place Sugita AVM Microclips during surgical procedures. | The Sugita AVM Microclips are designed for occlusion of fragile capillary vessels to stop bleeding from arteriovenous malformations and other analogous venous structures.<br><br>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. | The slim clip applier is used to open, close and apply permanent/temporary Aesculap YASARGIL titanium aneurysm clips. | **SAME** as the predicate device for the respective aneurysm clips |
| **Materials** | | | | |
| | Stainless Steel; Jaws: Elgiloy (cobalt-chromium-molybdenum alloy – ASTM F1058) | Stainless Steel; Jaws: Elgiloy (cobalt-chromium-molybdenum alloy – ASTM F1058) | Stainless Steel with proprietary coating | **SAME** as the reference device |
| **Technological Characteristics** | | | | |
| Designated Clips for use with the device | Sugita AVM Microclips. | Sugita AVM Microclips. | YASARGIL Titanium Aneurysm Clips (Standard and Mini). | **SAME** as the reference device |
| Design | Designed to open and close the clips, remove them from their packaging and aid in delivery to the surgical site. | Designed to open and close the clips, remove them from their packaging and aid in delivery to the surgical site. | Designed to open, close and apply permanent/temporary Aesculap YASARGIL Titanium Aneurysm Clips. | **SAME** |
| Latch | Yes | Yes | Yes | **SAME** |
| Non-Sterile | Yes | Yes | Yes | **SAME** |
| Cleaned prior to use by the end user | Validated cleaning instructions are provided | Cleaning instructions were provided | Yes | **Substantially Equivalent** |

## Non-clinical Performance Testing

Sterilization and cleaning validation testing was conducted to support the updated recommended steam sterilization and cleaning parameters for the subject device.

| Pre-vacuum Steam Sterilization Parameters | | |
|---|---|---|
| Sterilization Temperature | Retention Time | Drying Time |
| 132°C / 269.6°F | 4 minutes | 20 minutes |
| 134°C / 273.2°F | 3 minutes | 20 minutes |

Shelf-life

The Sugita AVM Microclip Applier does not have a shelf life because it is provided non-sterile and is constructed of inert materials.

Biocompatibility

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

## Conclusion

There have been no device design or material changes to the Sugita AVM Microclip Applier. Validated parameters for steam sterilization and cleaning are provided to update the Instructions for Use of the device and do not raise new questions of safety or effectiveness. The Sugita AVM Microclip Applier is substantially equivalent to the predicate device. Both devices have the same intended use and similar Indications for Use, technological characteristics and operating principles.