K990202

JUN 4 1999

510(k) Summary

Sugita Titanium Aneurysm Clip

Common/Classification Name: Intracerebral Aneurysm Clip, 21 CFR 882.5200

Mizuho America, Inc.
123 Brimbal Avenue
Beverly, MA 01915

978-921-1718
978-921-4003 (FAX)

Contact: Jon Macomber, Prepared: April 14, 1999

A. LEGALLY MARKETED PREDICATE DEVICES

The **Sugita Titanium Aneurysm Clip** is substantially equivalent to the Aesculap Titanium Aneurysm Clip which was cleared by FDA as K970050 on November 26, 1997. It is also substantially equivalent in some characteristics to the Sugita (Elgiloy) Aneurysm Clip, cleared for marketing under P820009 as a Class III device and reclassified into Class II on May 18, 1983, and to the Spetzler Ti-100 Titanium Aneurysm Clip cleared by FDA as K955064 on October 17, 1996.

B. DEVICE DESCRIPTION

The **Sugita Titanium Aneurysm Clip** is made from the titanium alloy Ti6Al4V. This alloy was chosen for the new clip because of its excellent compatibility with magnetic resonance imaging (MRI) devices. Titanium and its alloys cause much less artifact and are subject to much smaller magnetomechanical effects than other clips materials such as the cobalt-chrome alloys or stainless steel. Ti6Al4V also has excellent mechanical properties.

The Sugita Titanium Aneurysm Clips are available in 55 models of various shapes and sizes. These shapes and sizes are identical to the corresponding models of the Sugita Elgiloy clips.

C. INTENDED USE

The Sugita Titanium Aneurysm Clips of the permanent type are indicated for implantation for permanent occlusion of cerebral aneurysms. The temporary type are indicated for temporary occlusion

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of cerebral blood vessels.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Sugita Titanium Aneurysm Clip** is a medical device, and it has similar indications for use statement as the legally marketed Sugita Aneurysm Clip. However, the differences in indications statements do not change the intended therapeutic use. The **Sugita Titanium Aneurysm Clip** has the same technological characteristics and is made from the same material as the Aesculap Titanium Clip. For most of the characteristics, this premarket notification will describe the characteristics of the **Sugita Titanium Aneurysm Clip** in sufficient detail to assure substantial equivalence. One characteristic, mechanical properties, may not be precise enough to ensure equivalence, so laboratory data are submitted herein which demonstrate that the **Sugita Titanium Aneurysm Clip** is substantially equivalent to the predicate device with regard to mechanical properties.

E. TECHNOLOGICAL CHARACTERISTICS

The **Sugita Titanium Aneurysm Clip** is made from the titanium alloy Ti6Al4V. The 55 models manufactured in the titanium alloy are identical to the corresponding Sugita Elgiloy models in shape and size.

F. TESTING

As is discussed in detail elsewhere in this 510(k), the data show that after 500 openings and closings, the **Mizuho Titanium Aneurysm Clips** on average retain 98.5% of their original closing force (using the ASTM measurement technique). This compares with 97.1% for the Yasargil Titanium Clips. The MR safety and compatibility summary in **Section IV** demonstrates that the clip is safe for use in the MR environment up to 10 T, and that the artifact on MR images up to 1.5 T does not extend significantly beyond the region occupied by the clip. Streak artifact on CT images is minimal, much less than is seen with cobalt-chromium alloy clips.

G. CONCLUSIONS

The 510(k) decision algorithm brings us to a determination of Substantial Equivalence, as defined in the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 4 1999

Mizuho America, Inc.
c/o T. Whit Athey, Ph.D.
Senior Consultant
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K990202
Trade Name: Sugita Titanium Aneurysm Clip
Regulatory Class: II
Product Code: HCH
Dated: April 15, 1999
Received: April 15, 1999

Dear Dr. Athey:

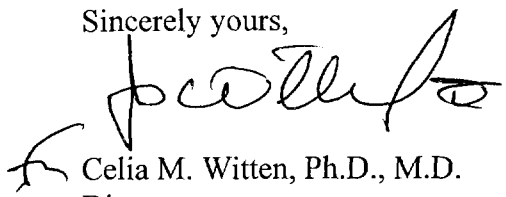
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K990202

Device Name: Sugita Titanium Aneurysm Clip

Indications For Use:

The Sugita Titanium Aneurysm Clips of the permanent type are indicated for implantation for permanent occlusion of cerebral aneurysms. The temporary type are indicated for temporary occlusion of cerebral blood vessels.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990202