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K960037

Mizuho America Inc.
123 Brimbal Avenue,
Beverly, MA 01915
800-699-CLIP(2547)
TEL: 508-921-1718
FAX: 508-921-4003



510(k) SUMMARY

Sugita AVM Microclip

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

Contact: Brian Connelly

Telephone: 508-921-1718
FAX: 508-921-4003

Submitted by: Curtin & Associates International
1200 East Street
Dedham, MA 02026

Contact: Donald A. Lincoln

Telephone: 617-329-1955
FAX: 617-329-2529

Date this Summary was prepared: INSERT DATE

Trade Name: Sugita AVM Microclip
Common Name: AVM Clip
Classification Name: Could not be determined

Legally Marketed Devices to Which Substantial Equivalence is claimed:

Sundt AVM Micro Clip - K902544

510(k) SUMMARY-continued
Sugita AVM Microclip

Description of Device: These devices are miniaturized versions of the currently marketed Sugita Aneurysm Clip. They are used to occlude small vessels when controlling bleeding on arteriovenous malformations or other similar venous structures.

Intended Use of the Device: Occlusion of small vessels as a compliment to bipolar coagulation.

Summary of Technological Characteristics: The devices are based in design upon a currently marketed spring action aneurysm clip. The material is the same, the production methods are the same, but the clip size is reduced to allow for the intended use.

Summary of test data:

CHANGES DURING STERILIZATION: The sample devices were subjected to sterilization at 250°F using a 20 minute cycle. This was repeated 50 times with the closing force being measured before the first cycle and at the conclusion of the test. The change in closing force for all clips tested was less than 10%.

MULTIPLE OPENING TESTING: Sample clips were subjected to 100 openings and closings. The results showed that holding force changed less than 10%.

TWIST TESTING: Samples were subjected to a twisting motion to determine the clips ability to return to its initial configuration. All clips passed.

MRI COMPATIBILITY: Sample clips were subject to testing in a 1.5 Tessler field. The angle of deflection for the clips tested was less than 3.5°.