

K970050



NOV 26 1997

510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990

Yasargil Titanium Aneurysm Clips

January 3, 1997

Submitted by: Aesculap[®], Inc.
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Product: Yasargil Titanium Aneurysm Clips
Common Name: Aneurysm Clips

- A. **Device Description**
These titanium alloy aneurysm clips will be available in mini and standard sizes, and as temporary or permanent devices.
- B. **Intended Use:**
The intended use of the Yasargil Titanium Alloy aneurysm clips is to occlude cerebral aneurysms in either a temporary or permanent manner. They are applied by Aesculap clip appliers with titanium alloy jaws
- C. **Technological Characteristics:**
With exception of device material, the Yasargil Titanium Alloy aneurysm clips do not incorporate any new technological characteristics when compared to Aesculap's Yasargil Phynox aneurysm clips or to other legally marketed devices. The titanium alloy clips share similar tolerances, manufacturing controls, packaging and labeling as the current Phynox clips.

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D. Material Composition / Biocompatibility

The material composition is titanium alloy (Ti6AL4V). The alloy composition and properties conforms with ISO Standard 5832/3: *"Implants for Surgery Metallic Materials - Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy"* and ASTM standard F136: *"Specification for Wrought Titanium 6AL-4V Eli Alloy for Surgical Implant Applications"*.

A neurological implantation study was conducted on Aesculap's titanium alloy aneurysm clips to evaluate biocompatibility of these devices. The study evaluated the potential of these clips to induce neurotoxicity after implantation in the cerebrum (brain parenchyma) and within the subarachnoid space of albino rabbits after 90, 140 and 180 days. No significant clinical observations, including any neurobehavioral findings or weight changes, were made in either the test or control implanted animals during the 180-day study. These findings are consistent with the biocompatibility study conducted on the titanium Spetzler Ti 100 Aneurysm Clips which have received marketing clearance from the Food and Drug Administration (*subject to #K955064*).

E. Mechanical, Metallurgical and MRI Testing of the Final Product

Studies done on the various stages in the production of the clips using scanning electron microscopy, metallography and energy dispersive x-ray analysis show that the production process does not effect the mechanical and metallurgical integrity of the titanium alloy material. Studies of the device following grinding, bending and adjustment production steps fails to disclose surface or subsurface cracks. Analysis of the laser welding site shows good mechanical properties without inadmissible gas absorption. Metallographic studies show no significant changes in the heat-affected zone, and surface studies indicate adequate removal of thin oxide layers.

The closing force of each Yasargil Titanium Alloy clips has also been tested and is found to be comparable to the currently marketed Yasargil Phynox aneurysm clips.

The various magnetic resonance imaging tests clearly demonstrated the superiority of the titanium alloy material as compared to stainless steel and cobalt-based alloy materials. All materials were non-ferromagnetic; the titanium alloy had detectable weaker paramagnetic properties than the Phynox or non-martenistic stainless steel.

The titanium alloy clips showed no detectable deflections or torsions at any magnetic field strength, including the 4.7T level. The artifacts caused by titanium implants in both the nuclear spin resonance and CT scans *are substantially reduced* due to the titanium alloy material. The magnetic field did not induce any measurable heating effect on the clips. *All testing indicates the titanium alloy aneurysm clips are safe, effective, and compatible with current diagnostic imaging equipment.*

F. Design Comparison

The Yasargil titanium aneurysm clips are very similar or are identical to the current Yasargil Phynox clip patterns. The titanium clip product line has been expanded to include additional temporary clip patterns.

Additionally, the titanium alloy aneurysm clips share similar features, dimensions and styles to Spetzler Ti 100 Aneurysm Clips, (*subject to #K955064*) by Elekta Instruments, Codman occlusion clips (*#K760771*) such as Sundt-Kees Slim-Line Aneurysm Clips and McFadden Vari-Angle Aneurysm clips as well as to Sugita Aneurysm clips (*subject to #K782040*) by Downs Surgical, manufactured by Mizuho Medical Co. Ltd.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Victoria Mackinnon
Manager, Regulatory Affairs
Aesculap, Inc.
1000 Gateway Boulevard
South San Francisco, California 94080-7030

Re: K970050
Trade Name: Yasargil Titanium Aneurysm Clips
Regulatory Class: II (two)
Product Code: 84 HCH
Dated: September 4 1997
Received: September 5, 1997

Dear Ms. Mackinnon:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): N/A

Device Name:

Yasargil Titanium Aneurysm Clips.

Indication for Use:

The Yasargil Titanium Aneurysm Clips presented in this submission are intended for occlusion of cerebral aneurysms in either a temporary or permanent manner. They are applied by Aesculap clip appliers with titanium alloy jaws.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Barbara Zimmerman
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970050