DEC 18 1998

K983758

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

Yasargil Titanium Aneurysm Clips

October 23, 1998

Submitted by: Aesculap®, Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080
Contact: Victoria Mackinnon
Phone: (650) 624-5070
FAX: (650) 589-3007

Product: Yasargil Titanium Aneurysm Clips
Common Name: Aneurysm Clips

A. Device Description
These titanium alloy aneurysm clips will be available 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:
The additional patterns of Yasargil Titanium Alloy aneurysm clips do not incorporate any new technological characteristics when compared to Aesculap's current Yasargil Titanium or 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 and Titanium aneurysm clips.

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*".

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E. Substantial Equivalence

These additional patterns of Yasargil titanium aneurysm clips are very similar or are identical to the current Yasargil titanium alloy 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

DEC 18 1998

Victoria Mackinnon
Director, Regulatory Affairs
AESCULAP, Inc.
1000 Gateway Boulevard
South San Francisco, California 94080-7030

Re: K983758
Trade Name: Yasargil Titanium Aneurysm Clips
Regulatory Class: II
Product Code: HCH
Dated: October 23, 1998
Received: October 26, 1998

Dear Ms. Mackinnon:

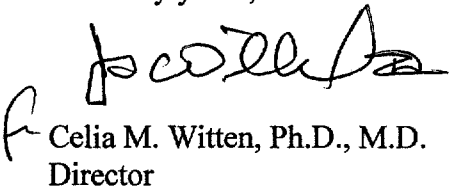
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

K983758

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 ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983758