2/12/99

K984109

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

AESCULAP AXIAL CLIP APPLIERS

November 13, 1998

Company

Aesculap®, Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080

Contact

Lia S. Jones, Regulatory Associate
Phone: 650-624-5073
Fax: 650-589-3007
E-Mail: lia.jones@aesculap.com

Trade Name

Axial Clip Applier

Common Name(s)

Aneurysm Clip Applier
Applying Forceps

Product Code and Classification Name

84HCI; Aneurysm Clip Applier

Product Classification

Class II

Regulatory Classification

21 CFR § 882.4175

Intended Use

The Aesculap Axial Clip Appliers are used for holding and applying intracranial aneurysm clips.

Device Description

There are twelve Axial clip appliers; each with complete material and design compatibility with Aesculap's existing Yasargil titanium and phynox aneurysm clip patterns. The new Axial clip appliers are available in three lengths (70mm, 90mm, 110mm), two jaw sizes (mini and standard), and two jaw materials (phynox and titanium).

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Summary of Technological Characteristics

The new Axial clip appliers do not impart any new technological features or characteristics from Aesculap's current aneurysm clip appliers (Yasargil, Caspar and Vario) other than the slightly modified jaw design and the take-apart shaft. These minor modifications, however, do not affect the safety and effectiveness of the new Axial clip appliers, as demonstrated by the information submitted in this premarket notification.

Performance Data

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

However, the Axial clip appliers presented in this submission do conform to the following ASTM Standards:

F700-93: *Standard Practice for Care and Handling of Intracranial Aneurysm Clips and Instruments*

Proposed ASTM Standard 1B: *Specifications for the Requirements and Disclosure of Aneurysm Self-Closing Appliers*

Substantial Equivalence

Aesculap believes that its new Axial Clip Appliers are substantially equivalent in design, material composition, function and intended use as the following clip appliers currently in commercial distribution and cleared by the FDA:

- **Yasargil Clip Applying Forceps**
  by Aesculap, Inc. (K833651)
- **Aneurysm Clip Appliers**
  by Aesculap, Inc. (K940970)
- **Elekta Clip Appliers**
  by Elekta (K955064)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Ms. Lia S. Jones
Regulatory Associate
Aesculap
1000 Gateway Boulevard
South San Francisco, California 94080-7030

Re: K984109
Trade Name: Aesculap Axial Clip Appliers
Regulatory Class: II
Product Code: HCI
Dated: November 16, 1998
Received: November 17, 1998

Dear Ms. Jones:

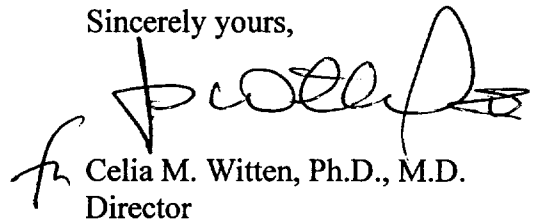
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

K954109

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: **Aesculap Axial Clip Appliers**

Indications for Use:

The Aesculap Axial Clip Appliers are used for holding and applying intracranial aneurysm clips.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984109

Prescription Use X or Over-the-Counter Use _____
(per 21 CFR 801.109)