

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

Aesculap MINOP System

December 15, 1998

Submitted by: **Aesculap[®], Inc.**
1000 Gateway Blvd.
So. San Francisco, CA 94080
Contact: Mary Ellen Holden
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Direct line: (650) 624-5072
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Product: Aesculap MINOP System
Common Name: Neuroendoscopes

Intended Use

Aesculap's MINOP System is intended for use in endoscope-assisted microneurosurgery and pure neuroendoscopy (i.e. ventriculoscopy) for direct visualization, diagnostic and/or therapeutic procedures such as ventriculostomies, biopsies and removal of cysts, tumors and other obstructions.

Technological Characteristics

The MINOP System consists of trocars (cannulas with blunt obturators), neuroendoscopes, instruments and electrodes. There are three different styles of operating cannulas which function as the base for the device system. The MINOP System operating cannulas have either 1, 3, or 4 working channels.

The Neuroendoscopes for the MINOP System are rigid, rod-lens neuroendoscopes with either 0° or 30° direction of view. The lens eyepiece is angled at 90° to allow an unobstructed view when used in conjunction with a surgical microscope. The MINOP System consists of reusable devices composed primarily of stainless steel.

An optional holding device, Aesculap's Flexible Titanium Support Arm, can be used to position and hold the neuroendoscopes. With use of the flexible support arm, the surgeon can freely operate with both hands.

Performance Standards

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, Aesculap's MINOP System complies with the requirements of IEC 601-2-18 (Medical electrical equipment, Part 2: Particular requirements for the safety of endoscopic equipment.) The MINOP System has undergone evaluation for electrical, thermal and irrigation safety to ensure the system is safe for the intended use.

Sterilization

The MINOP System is provided non-sterile and must be sterilized prior to use. The devices may be sterilized by steam sterilization.

Substantial Equivalence

Aesculap's MINOP System shares similar features and function with corresponding devices distributed by:

- Aesculap (Ventriculoscope, Angled Neuroendoscopes)
- Codman (Neuroendoscopes)
- Neuro Navigational (Neuroview)
- Richard Wolf (Neuro-Endoscope)



DEC 18 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary Ellen Holden
Senior Regulatory Associate
Aesculap, Inc.
1000 Gateway Boulevard
South San Francisco, California 94080-7030

Re: K983365
Trade Name: Aesculap MINOP System
Regulatory Class: II
Product Code: GWG
Dated: September 23, 1998
Received: September 24, 1998

Dear Ms. Holden:

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.

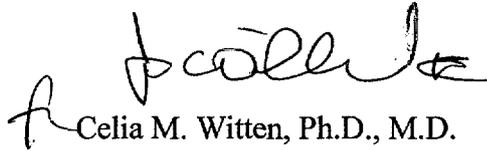
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,

A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name.

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

INDICATION FOR USE STATEMENT

510(k) Number (if known): 1K983365
~~N/A~~

Device Name:

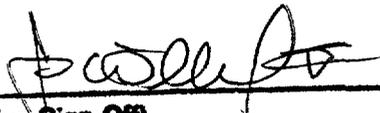
Aesculap MINOP System

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(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 1K983365

Prescription Use X
(Per 21 CFR 801.109)