MAR 1 8 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

K014149 1/2

PAEDISCOPE

December 12, 2001

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Georg Keller, Regulatory Affairs Manager
800-258-1946 (phone)
610-791-6882 (fax)
georg.keller@aesculap.com (email)

TRADE NAME: Paediscope

COMMON NAME: Neuroendoscope

DEVICE CLASS: NEUROENDOSCOPE CLASS II
MICRO-INSTRUMENTS – CLASS I EXEMPT

PRODUCT CODE: Neuroendoscope – 84 GWG
Micro-Instruments – 84 GZX

CLASSIFICATION: Neuroendoscope – 882.1480
Micro-Instruments – 882.4525

REVIEW PANEL: Neurology

INTENDED USE

Aesculap's **Paediscope** 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.

DEVICE DESCRIPTION

Aesculap's Paediscope combines the features of both flexible and rigid scopes. The distal end is a rigid neuroendoscope with a 3.0mm diameter. The rigid part includes one operating channel and two suction and irrigation channels. The flexible part ends at the standard adapters for light cables and eyepiece connection. The flexible outpatient part allows more flexibility and reduces the weight of the scope part introduced into the patient. The Paediscope can be used in adult and pediatric neuroendoscopies. The micro instruments are included with the Paediscope for the cutting and grasping biopsies and the removal of cysts, tumors and other obstructions.

PURPOSE FOR SUBMISSION

The purpose for this submission is to gain marketing clearance for the Paediscope.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, Aesculap's Paediscope comply with the requirements of IEC60601-2-18 (Medical electrical equipment, Part 2: Particular requirements for the safety of endoscopic equipment.) The Paediscope has undergone evaluation for electrical, thermal and irrigation safety to ensure the system is safe for the intended use.

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SUBSTANTIAL EQUIVALENCE

The new Paediscope described in this premarket notification is substantially equivalent to those predicate devices:

- Aesculap MINOP System (K983365)
- Aesculap Ventriculoscope System (K954394)
- Neuro Navigational Neuroview (K954899)
- Medtronic PSMedical Channel Neuroscope (K002572)
- Storz Miniature Neuroendoscope (K002704)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2002

Mr. Georg Keller
Regulatory Affairs Manager
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Re: K014149
Trade/Device Name: Paediscope
Regulation Number: 882.1480
Regulation Name: Neurological endoscope
Regulatory Class: II
Product Code: GWG
Dated: December 15, 2001
Received: December 18, 2001

Dear Mr. Keller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K014149

Device Name: Paediscope

Indication for Use:

Aesculap's **Paediscope** 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014149

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)