B. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 15 2006

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

CONTACT: Lisa M. Boyle, Regulatory Specialist
800-258-1946 (phone)
610-791-6882 (fax)
lisa.boyle@aesculap.com (email)

TRADE NAME: Aesculap Neuro Patties

COMMON NAME: Cottonoid Paddie

CLASSIFICATION NAME: Neurosurgical Paddie

REGULATION NUMBER: 882.4700

PRODUCT CODE: 84 HBA

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the Neurosorb Premium Patties are substantially equivalent to:

- Aesculap Neuro Patties (K031008)

DEVICE DESCRIPTION

Aesculap's Neuro Patties are rectangular fluid absorption pads for use during neurological and/or general procedures. The devices are available in a variety of dimensions and sizes. The neuro patties are manufactured from either a cotton or viscose fibers. All patties have a suture string attached for ease in count verification, they are also available with x-ray detectable markers if desired. The patties are packaged 10 per card in either single size sets or in procedure (indication) sets with a variety of sizes. These devices are provided sterile or non-sterile (for kit packager), single use only, and should not be resterilized.

INDICATIONS FOR USE

Aesculap's Neuro Patties are intended for use during surgery to protect nervous tissue, absorb fluids, or stop bleeding during neurological and other general procedures.

TECHNOLOGICAL CHARACTERISTICS (compared to predicate(s))

The Neurosorb Premium Pattie will be offered in similar in shapes and sized as the predicate devices. The Neurosorb Premium Paddie is manufactured from viscose, which is the same material as the existing predicate device.

PERFORMANCE STANDARDS

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2006

Aesculap, Inc.
% Ms. Lisa M. Boyle
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K062406
Trade/Device Name: Neuro Patties
Regulation Number: 21 CFR 882.4700
Regulation Name: Neurosurgical paddie
Regulatory Class: Class II
Product Code: HBA
Dated: August 17, 2006
Received: August 18, 2006

Dear Ms. Boyle:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K062406

Device Name: Neuro Patties

Indication for Use:

Aesculap's **Neuro Patties** are intended for use during surgery to protect nervous tissue, absorb fluids, or stop bleeding during neurological and other general procedures.

Prescription Use X and/or Over-the-Counter Use
(per 21 CFR 801.109) (21 CFR 897 Subpart C)

(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,
and Neurological Devices

510(k) Number K062406