APR - 5 2002

K020728

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

MIETHKE SHUNT SYSTEM

November 26, 2001

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

CONTACT: Joyce Kilroy, Director of Regulatory Affairs/Quality Assurance
800-258-1946 (phone)
610-791-6882 (fax)
joyce.kilroy @ aesculap.com (email)

TRADE NAME: Central Nervous System Fluid Shunt and Components

COMMON NAME: Miethke Shunt System

DEVICE CLASS: Shunt System - Class II
Ventricular Catheter - Class II

PRODUCT CODE: Shunt System - JXG
Ventricular Catheter - HCA

CLASSIFICATION: Shunt System - 882.5550
Ventricular Catheter - 882.4100

REVIEW PANEL: Neurology

INTENDED USE

The **Miethke Shunt System** is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.

DEVICE DESCRIPTION

The ventricular catheter is a part of the Miethke Shunt System. It is used to gain access to the cavities of the brain for removal of excess CSF.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The new Miethke Shunt System conforms to applicable ASTM and ISO standards.

SUBSTANTIAL EQUIVALENCE

The Aesculap Miethke Shunt System is essentially identical to the J & J Hakim Micro Programmable Valve System (K980778), Heyer-Schulte Novus (K961859), P/S Medtronic Bulton (K911410), P/S Medtronic Delta (K902783), Cordis NMT Gravity Compensating Accessory (K932429) and the Cordis NMT Hakim Standard/Pediatric Valves (K861377).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Joyce Kilroy
Director, Regulatory Affairs
and Quality Assurance
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

APR 5 2002

Re: K020728
Trade/Device Name: Miethke Shunt System
Regulation Number: 882.4100
Regulation Name: Ventricular Catheter
Regulatory Class: II
Product Code: HCA
Dated: March 4, 2002
Received: March 6, 2002

Dear Ms. Kilroy:

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,

for Mark N. Melkerson

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): K020728

Device Name: Miethke Shunt System

Indication for Use:

The **Miethke Shunt System** is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

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

510(k) Number K020728

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)