K062009

C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[in Accordance with SMDA of 1990]

Miethke proGAV® Shunt

12 January 2007

JAN 17 2007

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

Establishment Registration Number: 2916714

CONTACT: Matthew M. Hull, Regulatory Affairs Manager
800 258-1946 x 5072 (phone)
610 791-6882 (fax)

TRADE NAME: Aesculap® - Miethke proGAV® Programmable Shunt System

COMMON NAME: Hydrocephalus Shunt System

DEVICE CLASS: Class II

PRODUCT CODE: JXG

CLASSIFICATION: 21 CFR Section 882.5550: Central Nervous System fluid shunt and components

REVIEW PANEL: Neurology

INDICATIONS FOR USE

The Miethke proGAV® Programmable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum. Adjustments of the proGAV shunt can be verified by using the verification instrument but must be confirmed by radiograph (X-ray).

DEVICE DESCRIPTION

The proGAV® is a "programmable" shunt that can be set for a range of pressures. The valve in the new proGAV® is a leaf spring and ball mechanism that is mechanically controlled by internal magnets. The outer case for the device is made of titanium. The shunt comes with a manual device to verify the pressure setting and another to set or re-set the pressure. These manual accessories are both for external use by the physician. Once verified using the instrument the setting must be confirmed with an X-ray.
Various Miethke shunt system accessories such as shunt assistants, catheters, connectors, deflectors and reservoirs are also offered with the proGAV®.

PURPOSE FOR SUBMISSION

The purpose for this submission is to gain marketing clearance for the Miethke proGAV® Shunt.

PERFORMANCE DATA

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

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Aesculap® Miethke proGAV® Shunt is equivalent in materials and basic operational principles to the previously cleared Aesculap - Miethke Shunt System (K011030), the Sophy Polaris SPV Valve (K042481) by Sophysa S.A., Medtronic's Strata II Adjustable Valve (K042465), and the Hakim Programmable Valve System from Johnson & Johnson (K980778).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2007

Aesculap, Inc.
% Mr. Matthew M. Hull, RAC
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K062009
Trade/Device Name: Miethke proGAV® Programmable Shunt System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: November 21, 2006
Received: November 22, 2006

Dear Mr. Hull:

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.

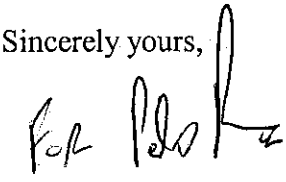
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K062009

Device Name: **Miethke proGAV® Programmable Shunt System**

Indication for Use:

The Miethke proGAV® Programmable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum. Adjustments of the proGAV shunt can be verified by using the verification instrument but must be confirmed by radiograph (X-ray).

Prescription Use X or Over-the-Counter Use _____

(Per 21 CFR 801.109)

(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 K062009