K103003

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Miethke proGAV Shunt
November 9, 2010

NOV - 9 2010

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com

COMMON NAME: Hydrocephalus Shunt System

CLASSIFICATION NAME: Aesculap Miethke proGAV Programmable Shunt System

REGULATION NUMBER: 882.5550

PRODUCT CODE: JXG

DEVICE DESCRIPTION

The proGAV is a "programmable" shunt that can be set for a range of pressures. The valve in the 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 . The proposed modification is to the internal magnet.

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).

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the modified proGAV Shunt is substantially equivalent to the proGAV Shunt of the Miethke proGAV Programmable Shunt System (K062009). The modified shunt is similar to the current proGAV Shunt. The only difference is the size of the internal magnets. The materials, design, principle of operation and intended use is equivalent to the previously cleared proGAV Shunt.

PURPOSE FOR PREMARKET NOTIFICATION

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

K103003

PERFORMANCE DATA

The following tests demonstrated the proGAV shunt is safe and effective.

- ASTM F2119 Evaluation of MR Image Artifacts
- ASTM F2182 Measurement of Radio Frequency Induced Heating During Magnetic Resonance Imaging
- ASTM F2213 Qualitative Measurement of Magnetically Induced Torque in the Magnetic Resonance Environment
- ASTM F2052 Measurement of Magnetically Induced Displacement Force on the in the Magnetic Resonance Environment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aesculap, Inc.
c/o Ms. Kathy A. Racosky
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

NOV - 9 2010

Re: K103003
Trade/Device Name: Aesculap Miethke proGAV Programmable Shunt System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: October 11, 2010
Received: October 12, 2010

Dear Ms. Racosky:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

NOV - 9 2010

510(k) Number: K103003

Device Name: Miethke proGAV Programmable Shunt System

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).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K103003