K110206

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

Miethke Shunt System miniNAV Valve
September 22, 2011

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 Shunt System

REGULATION NUMBER: 882.5550

PRODUCT CODE: JXG

DEVICE DESCRIPTION

The Miethke Shunt System miniNAV Valve is used in the treatment of hydrocephalus. The miniNAV Valve is a small cylindrical tube chamber with inlet and outlet connection ports at opposite ends. A "ball-in-cone-valve" is integrated in the inlet of the device. A spiral spring maintains the opening pressure of the ball-in-cone valve and a sapphire ball ensures the precise closure of the valve. The housing of the miniNAV Valve is manufactured from titanium. The miniNAV Valve is available as a single device as well as various Miethke shunt system accessories such as shunt assistants, catheters, connectors, deflectors and reservoirs.

The McLanahan reservoir is a flushing reservoir. It has an integrated occlusion mechanism which allows flushing in both the proximal and distal directions. The reservoir is used as a shunt component. The McLanahan reservoir is manufactured of silicone elastomer and titanium.

K110206

INDICATIONS FOR USE

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

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the miniNAV Valve and McLanahan reservoir of the Miethke Shunt System are substantially equivalent to the Paedi-GAV Valve and MonoStep Valve of the Miethke Shunt System (K011030) and Medtronic PS Medical Strata II Valve and Shunt Assembies with and without BioGlide (K042465). The new miniNAV Valve is similar to the current Paedi-GAV Valve and MonoStep Valve. The only differences are the size of the valve and a lower pressure opening. The materials, design, principle of operation and intended use is equivalent to the previously cleared Paedi-GAV Valve and MonoStep Valve of the Miethke Shunt System. The previously cleared system also included the ShuntAssistant component which has the same valve pressure level range as the miniNAV. The McLanahan reservoir has an integrated occlusion mechanism similar to the Strata II Valve.

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the new miniNAV Valve and McLanahan reservoir of the Miethke Shunt System.

PERFORMANCE DATA

Testing of the Aesculap Miethke Shunt System miniNAV Valve was performed in accordance with ISO 7197:2006 and results were found to be similar to other legally marketed predicate devices. In addition testing was performed according to the following MRI standards:

- 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

The results and evaluation conclude that the device is MR Conditional in 3-Tesla Magnetic Resonance Imaging (MRI) systems according to ASTM F 2503 and is substantially equivalent to the predicate devices.

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

OCT 2 7 2011

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

Re: K110206
Trade/Device Name: Aesculap Miethke Shunt System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: October 04, 2011
Received: October 05, 2011

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 STATEMENT

510(k) Number: K110206

Device Name: Miethke Shunt System

Indications for Use:

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

Prescription Use X and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K110206