DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 2, 2015

Aesculap, Inc.
Ms. Kathy Racosky
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K141687
Trade/Device Name: Aesculap - Miethke ProGAV 2.0 Adjustable 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: March 5, 2015
Received: March 6, 2015

Dear Ms. Kathy 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S FDA

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141687

Device Name
Aesculap Miethke proGAV 2.0 Adjustable Shunt System

Indications for Use *(Describe)*
The Miethke proGAV 2.0 Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum. Adjustments of the proGAV 2.0 shunt can be verified by using the proGAV 2.0 Compass but must be confirmed by radiograph (X-ray).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Miethke proGAV 2.0 Adjustable Shunt System

March 31, 2015

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

TRADE NAME: Aesculap Miethke proGAV 2.0 Adjustable Shunt System

COMMON NAME: Hydrocephalus Shunt System

CLASSIFICATION: Class II

CLASSIFICATION NAME: Shunt, Central Nervous System and Components

REGULATION NUMBER: 882.5550

PRODUCT CODE: JXG

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the Aesculap Miethke proGAV 2.0 Adjustable Shunt System is substantially equivalent to the Miethke proGAV Programmable Shunt System (K062009 / K103003). The proGAV 2.0 has some differences in technological features in comparison to the predicate device. There is no difference between the subject device and the predicate with respect to indications for use.

DEVICE DESCRIPTION

proGAV 2.0 is an adjustable differential pressure valve that can be set for a range of pressures. The proGAV 2.0 valve is comprised of a titanium housing that contains a leaf spring and ball mechanism that is mechanically controlled by internal magnets. Manual devices are available to locate, verify the pressure setting and to set or re-set the pressure pre and postoperatively. These manual accessories are for external use by the physician. Once verified using the Compass the setting must be confirmed with an X-ray. The device will be distributed by itself or in combination with the ShuntAssistant valve or proSA valve. The proGAV 2.0 adjustable differential pressure valve includes the same legally marketed accessories that are available with the Miethke Shunt Systems.

INDICATIONS FOR USE

The Miethke proGAV 2.0 Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum. Adjustments of the proGAV 2.0 shunt can be verified by using the proGAV 2.0 Compass but must be confirmed by radiograph (X-ray).

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Miethke proGAV 2.0 Adjustable Shunt System is substantially equivalent to the predicate Miethke proGAV Programmable Shunt System. The subject device is shown to be substantially equivalent and has the same performance characteristic to its predicate device through comparison in design, principles of operation, intended use, and materials. The proGAV and proGAV 2.0 device characteristics are summarized below.

	New Device Miethke Shunt System proGAV 2.0 Valve	Predicate Miethke Shunt System proGAV Valve K103003/K062009
Adjustable:	Yes	Yes
Valve Type:	Adjustable differential pressure	Adjustable differential pressure
Pressure levels:	0 – 20 cmH_2O	0 – 20 cmH_2O
Materials:		
Titanium Alloy Ti6Al4V	Yes	Yes
Neodym Ferrite Boron	Yes	Yes
Alpha Sapphire	Yes	Yes
Design:	Circular	Circular
Housing:		
Inner	smooth	N/A
Outer	thin curved wave profile	smooth
Audible or tactile feedback	Yes	No
Dimensions:		
Height	4.5 mm	4.4 mm
Diameter	17 mm	18 mm
# of Magnets	4	2
Sterilization:	Steam	Steam
Packaging:	Double Peel Pouch	Double Peel Pouch
Manual Instruments:	Yes	Yes
Tool settings and readings	0 – 20 cmH_2O	0 – 20 cmH_2O
Packaging	PE case or wooden box (set)	PE case

PERFORMANCE DATA

The below preclinical testing was performed to demonstrate that the Aesculap Miethke proGAV 2.0 Adjustable Shunt System performs as intended and is substantially equivalent to the predicate device. Testing was conducted in accordance with ISO 7197:2009.

Test	Test Method Summary	Results
Resistance to Leakage	100 cm of air applied to the subject device submerged in water. No leakage is allowed with a differential pressure from the inside to outside of 100 cm water column within 5 min.	No leakage detectable within 5 min under 100cm applied overpressure. Samples passed the acceptance criteria
Pressure-Flow	Pressure-flow-performance tested between the flow range of 5 to 50 ml/h. The measured pressure has to remain inside manufacturers declaration.	The pressure flow performance of each tested valve remains inside manufacturers declaration. Samples passed the acceptance criteria
Overpressure	Function and integrity of the subject device shall withstand a positive pressure of 1 m water column applied to the open shunt.	Valve function/performance was verified due to an additional measurement of the pressure flow performance after applying the overpressure. Integrity was verified by passing the dynamic braking force. Samples passed the acceptance criteria
Dynamic Break Strength	Using a frequency of 1 Hz ±0.2, tension is applied in flow direction and should lead to an elongation of the subject device of 10% or a maximum force of 5 N. Testing is carried out for 100,000 cycles.	No sample had a rupture or crack after applying 100 000 cycles. Samples passed the acceptance criteria
Bursting Pressure	Subject device must withstand a positive pressure of 2 m of water column inside the subject device without any change within a tolerance of ± 10% (no later than 2 hours after the burst pressure application).	No later than 2 hours after applying the positive pressure of 2m water column the valve pressure flow performance was inside manufacturers declaration. Samples passed the acceptance criteria
Reflux performance	To verify resistance a water bath was used for the 500 mm of water column against the flow direction of the subject device. A maximum flow of 0.04 ml/min is allowed to be drained back.	All tested items had a measured reflux lower that allowed. Samples passed the acceptance criteria
Long Term Stability	The subject device was immersed in distilled water and kept at 36°C ±5 while pumping distilled water at an average flow rate of 20 ml/h through the valve for at 28 days. Flow rate was check 3 times a day. Patient position was simulated (14 days/ horizontal and 14 days/ vertical)	All items remained inside the manufacturers declaration over the period of 28 days. Samples passed the acceptance criteria
Valve adjustability/readability	Different materials with varying thicknesses were placed between the valve and the adjustment/verification tools to verify the adjustability/verification of the valve	The adjustability and verification of all items remained inside the manufacturers declaration. Samples passed the acceptance criteria

Results of the above testing demonstrates that the device is substantially equivalent to the predicate device.

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 device.