July 5, 2019

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

Re: K190174
Trade/Device Name: Miethke Shunt System GAV 2.0 and SA 2.0 Valves
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: June 3, 2019
Received: June 3, 2019

Dear 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Xiaolin Zheng, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190174

Device Name
Miethke Shunt System GAV 2.0 and SA 2.0 Valves

Indications for Use *(Describe)*
The Miethke Shunt System GAV 2.0 and SA 2.0 are used for cerebrospinal fluid (CSF) shunting.

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.

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

Miethke Shunt System

January 31, 2019

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@aesculapimplants.com

TRADE NAME: Miethke Shunt System GAV 2.0 and SA 2.0 Valves

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

The Miethke Shunt System GAV 2.0 and SA 2.0 valves are substantially equivalent to the predicate, Aesculap Miethke Shunt System (K011030) and reference devices, Aesculap Miethke Shunt System (K110206/K031303)

DEVICE DESCRIPTION

The Aesculap Miethke Shunt System is used in the treatment of hydrocephalus. Components of the Miethke Shunt System can include the GAV (Gravity Assisted Valve) 2.0 valve and SA (SHUNTASSISTANT) 2.0 valve.

The GAV 2.0 is a posture dependent, fixed gravitational valve that combines a differential pressure unit and gravitational unit. This combination allows an automatic adjustment of the opening pressure according to the patient's different body position and is used to control overdrainage. The housing of the GAV 2.0 valve is manufactured from titanium. The GAV 2.0 valve is available in three models, each model is offered in six pressure level settings in various accessory configurations. The GAV 2.0 valve is available as a single device as well as with various Miethke shunt system accessories such as catheters, connectors, deflectors and reservoirs.

The SA 2.0 valve is a posture dependent gravitational valve and is used to control overdrainage. The SA 2.0 is designed for use in combination with an adjustable or non-adjustable differential pressure valve to add increased resistance to the shunt system as a patient changes position. housing of the SA 2.0 valve is manufactured from titanium. The SA 2.0 valve is available in three models, each model is offered in six pressure level settings in various accessory configurations. The SA 2.0 valve is available as a single device as well as with the proGAV 2.0 valve and various Miethke shunt system accessories such as catheters, connectors, deflectors and reservoirs.

INDICATIONS FOR USE

The Miethke Shunt System GAV 2.0 and SA 2.0 are used for cerebrospinal fluid (CSF) shunting.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Miethke Shunt System GAV 2.0 and SA 2.0 valves are substantially equivalent to the predicate Aesculap Miethke Shunt System (K011030) and reference devices, Aesculap Miethke Shunt System (K110206/K031303). The GAV 2.0 valve is similar to the paediGAV, GAV and DualSwitch valves of the Miethke Shunt System (K031303/K011030). The SA 2.0 valve is similar to the paediSA, SA and DualSwitch valves of the Miethke Shunt System (K110206/K011030). 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 GAV 2.0 and SA 2.0 device characteristics are summarized below.

	New Device Miethke Shunt System GAV 2.0 and SA 2.0 Valves		Predicate Miethke Shunt Systems (K011030)		
GAV 2.0 Valve:					
Valve Type:	Combined gravitational unit w/ ball-in-cone valve		Combined gravitational unit w/ ball-in-cone valve		Same
Version:	ventriculo-peritoneal & lumboperitoneal		ventriculo-peritoneal lumboperitoneal		Same
Pressure level (cmH_2O) combinations:	Lying position	Upright position	Lying position	Upright position	Similar The opening pressure level combinations fall within the range of the pressure levels of the predicate device. The only difference is three different pressure range combinations, which do not impact the functionality or intended use when compared to the predicate device.
	5	20, 25, 30, 35	4	14, 19, 24	
	10	25, 30	9	19, 24, 29	
			5	30, 35, 40	
			10	30, 40, 50	
Materials:					
Housing	Titanium Alloy Ti6Al4V		Titanium Alloy Ti6Al4V		Same
Ball --ball-in-cone unit --gravitational unit	Alpha Sapphire & Tantalum Alpha Sapphire		Alpha Sapphire & Tantalum Alpha Sapphire		Same
Spring	Titanium		Stainless Steel or Titanium Alloy Ti6Al4V		Same (Titanium Alloy Ti6Al4V)

Spring Shape:	Micro spiral		Cylindrical coil		Similar The subject device has a smaller and slightly different shape spring than the predicate device. Any differences are minor and and do not impact the functionality or intendied use when compared to the predicate device.	
Design:	Cylindrical tube and U shaped		Cylindrical tube		Similar The subject device is offered in an additional U shape design, which does not impact the functionality or intended use when compared to the predicate device.	
Dimensions:						
Height	4.2 mm and 8.6 mm		4.0 mm and 4.6 mm		Similar	The subject device has slightly different dimensions than those of the predicate device and any differences are minor and do not impact the functionality or intended use when compared to the predicate device.
Diameter	4.2 mm		4.0 mm and 4.6 mm		Similar	
Length	20.6 mm, 21.4 mm and 22.2		24.0 mm and 27.4 mm		Similar	
SA 2.0 Valve:						
Valve Type:	Gravitational		Gravitational		Same	
Version:	ventriculo-peritoneal & lumboperitoneal		ventriculo-peritoneal lumboperitoneal		Same	
Pressure levels (cmH_2O) combinations:	Lying position	Upright position	Lying position	Upright position	Same	
	0	10	0	10		
	0	15	0	15		
	0	20	0	20		
	0	25	0	25		
	0	30	0	30		
	0	35	0	35		
Materials:						
Housing	Titanium Alloy Ti6Al4V		Titanium Alloy Ti6Al4V		Same	
Ball	Alpha Sapphire & Tantalum		Alpha Sapphire & Tantalum		Same	
Design:	Cylindrical tube and U shaped		Cylindrical tube		Similar The subject device is offered in an additional U shape design, which does not impact the functionality or intended use when compared to the predicate device.	

Dimensions:				
Height	4.2 m and 8.6 mm	4.0 mm and 4.6 mm	Similar	The subject device has slightly different dimensions than those of the predicate devices and any differences are minor and do not impact the functionality or intended use when compared to the predicate device.
Diameter	4.2 mm	4.0 mm and 4.6 mm	Similar	
Length	19.0 mm, 20.0 mm and 20.8 mm	19.5 mm and 23.3mm	Similar	
GAV 2.0 & SA 2.0:				
MR labeling:	Added MR Conditional information and MRI Safety Section	N/A	Added MR Conditional information per ASTM F 2503 and MRI Safety Section to labeling per FDA Guidance Document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" to reflect MR testing	
Sterilization:	Steam	Steam	Same	
Packaging:	Double Peel Pouch	Double Peel Pouch	Same	

PERFORMANCE DATA

The following performance data is provided in support of the substantial equivalence determination. The below table summarizes the design verification activities. All samples met predefined acceptance criteria and the proposed devices passed design verification test activities. The test results demonstrate that the Aesculap Miethke GAV 2.0 valve and SA 2.0 valve of the Miethke Shunt System performs as intended and is substantially equivalent to the predicate device. Testing was conducted in accordance with ISO 7197:2006 standard for shunt safety and performance including the identified stated clauses.

Test	Test Method Summary	Results
Performance testing	4.2 - Radiopactiy 4.3 - Biocompatibility 4.5 - Control of the implanted shunt 4.6 - Pressure flow characteristics 4.7 - Identification of shunts in vivo 4.8 - Ability to withstand overpressure 4.9 - Dynamic breaking strength 4.10 – Behavior under MR imaging 4.11 – Bursting pressure 5.1.1 – Reflux performance 5.1.2 – Long term stability 5.1.3 – Influence of the changed posture of the patient on the valve performance	Pass

Results of the performance testing demonstrates that the device is substantially equivalent to the predicate device. The minor differences between the GAV 2.0 valve and SA 2.0 valve and the predicate devices raise no new issues of safety or effectiveness

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.