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

February 27, 2017

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

Re: K161853
Trade/Device Name: Miethke proGAV Programmable Shunt System, Miethke proGAV 2.0 Adjustable Shunt System, Miethke proSA 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: January 20, 2017
Received: January 23, 2017

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 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,

Carlos L. Pena -S

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)*
K161853

Device Name
Miethke proGAV Programmable Shunt System
Miethke proGAV 2.0 Adjustable Shunt System
Miethke proSA Adjustable Shunt System

Indications for Use *(Describe)*

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

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.

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

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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"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."

510(k) SUMMARY

Miethke proGAV Programmable Shunt System
February 15, 2017

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 Programmable 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

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. Various Miethke shunt system accessories such as shunt assistants, catheters, connectors, deflectors and reservoirs are also offered with the proGAV .

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.

SUBSTANTIAL EQUIVALENCE

Comparative information presented in the 510(k) supports the substantial equivalence of the subject proGAV Programmable Shunt System to the predicate proGAV Programmable Shunt System (K062009 / K103003). The proGAV Programmable Shunt System is substantially equivalent to the identified predicate with respect to performance characteristics, design, principles of operation and materials. The difference between the subject device and the

predicate is the removal of the required radiographic verification stated in the indications for use and labeling.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Miethke proGAV Programmable 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, and materials. The proGAV device characteristics are summarized below.

	Miethke proGAV Programmable Shunt System	**Miethke proGAV Programmable Shunt System**
	K161853	**K103003/K062009**
Indication:	The Miethke proGAV Programmable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.	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).
Adjustable	Same	Yes
ValveType	Same	Adjustable differential pressure
Material:		
Housing	Same	Titanium Alloy Ti4Al6V
Magnets	Same	Neodym Ferrite Boron
Ball	Same	Alpha Sapphire
Spring	Same	Titanium Alloy Ti4Al6V
Design	Same	Circular
Magnet:		
# of magnets	Same	2
Dimensions	Same	1.5 x 1.5 mm
Volume	Same	5.3 mm^3
Pressure levels:	Same Same	Adjustable 0 - 20 cmH_2O
Sterile/ Single Use	Same	Yes
Sterilization	Same	Steam
Packaging:	Same	Double Peel Pouch

	Miethke proGAV Programmable Shunt System **K161853**	**Miethke proGAV Programmable Shunt System** **K103003/K062009**
Tools:		
Verification tool	Same	Manually wipe with an alcohol base cleaner (>75% alcohol). May not be re-sterilized.
Masterdisc		
Verification Compass		
Adjustment tool		
Adjustment disc		
Check-mate	Same	For use in a sterile surgical field. Sterile, reusable, may be re-sterilized
Tool settings and readings:	Same	0 - 20 cmH_2O

PERFORMANCE DATA

Bench testing on the proposed device, proGAV Programmable Shunt System, included the following:

- Verification testing assessing the measurement agreement between X-ray confirmation and the proGAV Verification Tool when used with the proGAV Programmable Shunt System
- Verification testing assessing the measurement agreement between X-ray confirmation and the proGAV Verification Compass when used with the proGAV Programmable Shunt System

Test results demonstrated the substantial equivalence between the required radiographic verification method and the non-invasive method with the proGAV Verification Tool and proGAV Verification Compass. The test results met the acceptance criteria. Results of verification testing have demonstrated that the proposed proGAV Programmable Shunt System is substantially equivalent to the predicate proGAV Programmable Shunt System.

510(k) SUMMARY

Miethke proGAV 2.0 Adjustable Shunt System
February 15, 2017

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 Meithke proGAV 2.0 Programmable 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

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. 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.

SUBSTANTIAL EQUIVALENCE

Comparative information presented in the 510(k) supports the substantial equivalence of the subject proGAV 2.0 Adjustable Shunt System to the predicate proGAV 2.0 Adjustable Shunt

System (K141687). The proGAV 2.0 Adjustable Shunt System is substantially equivalent to the identified predicate with respect to performance characteristics, design, principles of operation and materials. The difference between the subject device and the predicate is the removal of the required radiographic verification stated in the indications for use and labeling.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Miethke proGAV 2.0 Adjustable Shunt System is substantially equivalent to the predicate Miethke proGAV 2.0 Adjustable 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, and materials. The proGAV 2.0 device characteristics are summarized below.

	Miethke *proGAV 2.0 Adjustable* Shunt System	**Miethke *proGAV 2.0 Adjustable* Shunt System**
	K161853	**K141687**
Indication:	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.	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 verification instrument but must be confirmed by radiograph (X-ray).
Adjustable	Same	Yes
ValveType:	Same	Adjustable differential pressure
Material:		
Housing	Same	Titanium Alloy Ti4Al6V
Magnets	Same	Neodym Ferrite Boron
Ball	Same	Alpha Sapphire
Spring	Same	Titanium Alloy Ti4Al6V
Design	Same	Circular
Magnet:		
# of magnets	Same	4
Dimensions	Same	1.5 x 1.5 mm
Volume	Same	10.6 mm^3
Pressure levels:	Same Same	Adjustable 0 – 20 cmH_2O
Sterile/ Single Use	Same	Yes
Sterilization	Same	Steam
Packaging:	Same	Double Peel Pouch

	Miethke *proGAV 2.0 Adjustable* Shunt System	**Miethke *proGAV 2.0 Adjustable* Shunt System**
	K161853	**K141687**
proGAV 2.0 Tools:		
Compass Adjustment tool	Same	Manually wipe with an alcohol base cleaner (>75% alcohol). May not be re-sterilized.
Compatible w/ proGAV Tools:	Same	Verification tool, Verification compass, Master disk, Adjustment tool, Adjustment disk, Check-mate
Tool settings and readings:	Same	0 – 20 cmH_2O

PERFORMANCE DATA

Bench testing on the proposed device, proGAV 2.0 Adjustable Shunt System, included the following:

- Verification testing assessing the measurement agreement between X-ray confirmation and the proGAV 2.0 Compass when used with the proGAV 2.0 Adjustable Shunt System
- Verification testing assessing the measurement agreement between X-ray confirmation and the proGAV Verification Compass when used with the proGAV 2.0 Adjustable Shunt System
- Verification testing assessing the measurement agreement between X-ray confirmation and the proGAV Verification Tool when used with the proGAV 2.0 Adjustable Shunt System

Test results demonstrated the substantial equivalence between the required radiographic verification method and the non-invasive method with the proGAV 2.0 Compass, proGAV Verification Compass and proGAV Verification Tool. The test results met the acceptance criteria. Results of verification testing have demonstrated that the proposed proGAV 2.0 Adjustable Shunt System is substantially equivalent to the predicate proGAV 2.0 Adjustable Shunt System.

510(k) SUMMARY

Miethke proSA Adjustable Shunt System
February 15, 2017

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 proSA 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

DEVICE DESCRIPTION

proSA is an adjustable gravitational valve that can be set for a range of pressures. The proSA valve is comprised of a titanium housing that contains a tantalum weight, leaf spring and ball mechanism that is mechanically controlled by internal magnets. Several manual devices are available to 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. The device will be distributed by itself or in combination with the miniNAV valve or proGAV valve. The proSA adjustable gravitational valve includes the same legally marketed accessories that are available with the Miethke Shunt Systems.

INDICATIONS FOR USE

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

SUBSTANTIAL EQUIVALENCE

Comparative information presented in the 510(k) supports the substantial equivalence of the subject proSA Adjustable Shunt System to the predicate proSA Adjustable Shunt System

(K120559). The proSA Adjustable Shunt System is substantially equivalent to the identified predicate with respect to performance characteristics, design, principles of operation and materials. The difference between the subject device and the predicate is the removal of the required radiographic verification stated in the indications for use and labeling.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Miethke proSA Adjustable Shunt System is substantially equivalent to the predicate Miethke proSA Adjustable 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, and materials. The proSA device characteristics are summarized below.

	Miethke proSA Adjustable Shunt System	**Miethke proSA Adjustable Shunt System**
	K161853	**K120559**
Indication:	The Miethke proSA Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.	The Miethke proSA Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum. Adjustments of the proSA shunt can be verified by using the verification instrument but must be confirmed by radiograph (X-ray).
Adjustable	Same	Yes
ValveType	Same	Adjustable Gravitational valve
Material:		
Housing	Same	Titanium Alloy Ti4Al6V
Magnets	Same	Neodym Ferrite Boron
Ball	Same	Alpha Sapphire
Spring	Same	Titanium Alloy Ti4Al6V
Weight	Same	Tantalum
Design	Same	Circular
Magnet:		
# of magnets	Same	2
Dimensions	Same	1.5 x 1.5 mm
Volume	Same	5.3 mm^3
Pressure levels:	Same Same	Adjustable 0 - 40 cmH_2O
Sterile/ Single Use	Same	Yes
Sterilization	Same	Steam
Packaging:	Same	Double Peel Pouch

	Miethke proSA Adjustable Shunt System	**Miethke proSA Adjustable Shunt System**
	K161853	**K120559**
Tools:		
Verification tool	Same	Manually wipe with an alcohol base cleaner (>75% alcohol). May not be re-sterilized.
Masterdisc		
Verification Compass		
Adjustment tool		
Adjustment disc		
Check-mate	Same	For use in a sterile surgical field. Sterile, reusable, may be re-sterilized
Tool settings and readings:	Same	0 - 40 cmH_2O

PERFORMANCE DATA

Bench testing on the proposed device, proSA Adjustable Shunt System, included the following:

- Verification testing assessing the measurement agreement between X-ray confirmation and the proSA Verification Tool when used with the proSA Adjustable Shunt System
- Verification testing assessing the measurement agreement between X-ray confirmation and the proSA Verification Compass when used with the proSA Adjustable Shunt System

Test results demonstrated the substantial equivalence between the required radiographic verification method and the non-invasive method with the proSA Verification Tool and proSA Verification Compass. The test results met the acceptance criteria. Results of verification testing have demonstrated that the proposed proSA Adjustable Shunt System is substantially equivalent to the predicate proSA Adjustable Shunt System.