November 21, 2019

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

Re: K192266
Trade/Device Name: M.blue 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: August 22, 2019
Received: August 23, 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,

Xiaolin Zheng, Ph.D.
Director (*Acting*)
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)*
K192266

Device Name
M.blue Adjustable Shunt System

Indications for Use *(Describe)*

The M.blue Adjustable Shunt System is 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.

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

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

Aesculap Miethke M.blue Adjustable Shunt System

October 25, 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@aesculap.com

TRADE NAME: M.blue 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 M.blue Adjustable Shunt System is substantially equivalent to the predicate, Aesculap Miethke proSA Adjustable Shunt System (K161853) and reference device, Miethke Shunt System miniNAV Valve (K110206).

DEVICE DESCRIPTION

M.blue is an adjustable valve that combines an adjustable gravitational unit and a fixed differential pressure unit. The M.blue valve can be set for a range of pressures and is offered in four pressure level settings. The M.blue valve is comprised of a titanium housing enclosed by a thin titanium membrane with a curved wave profile design. The gravitational unit of the M.blue valve contains a tantalum weight, leaf spring and ball mechanism that is mechanically controlled by internal magnets. The differential pressure unit (ball-in-cone) of the M.blue valve contains a sapphire ball and titanium spring.

Manual devices are available to locate, verify the pressure setting and to set or change the pressure pre and postoperatively. These manual accessories are for external use by the Healthcare provider.

The M.blue valve will be distributed by itself or in combination with the proGAV 2.0 valve. The M.blue valve includes the same legally marketed accessories that are available with the Miethke Shunt Systems.

INDICATIONS FOR USE

The M.blue Adjustable Shunt System is used for cerebrospinal fluid (CSF) shunting.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Miethke M.blue Adjustable Shunt System is substantially equivalent to the predicate, Aesculap Miethke proSA Adjustable Shunt System (K161853) and reference device, Miethke Shunt System miniNAV Valve (K110206). The M.blue has some differences in technological features in comparison to the predicate device. The subject device has the same intended use, design principles, operational principles and materials. The M.blue valve is also similar to the reference device. The M.blue device characteristics are summarized below.

	New Device Aesculap Miethke M.blue Adjustable Shunt System	Predicate Aesculap Miethke proSA Adjustable Shunt System K161853	Reference Device Aesculap Miethke Shunt System miniNAV Valve K110206
Adjustable:	Yes	Yes	No
Valve Type:	Adjustable Gravitational with integrated differential pressure unit	Adjustable Gravitational	Differential pressure
Pressure levels:			
--Gravitational unit	Adjustable 0 – 40 cmH_2O	Adjustable 0 – 40 cmH_2O	No
--Differential unit	Four pressure ranges 0 cmH_2O 5 cmH_2O 10 cmH_2O 15 cmH_2O	N/A	Four pressure ranges 0 cmH_2O 5 cmH_2O 10 cmH_2O 15 cmH_2O
Materials:			
Housing	Titanium Alloy Ti6Al4V	Titanium Alloy Ti6Al4V	Titanium Alloy Ti6Al4V
Rotor	Titanium Alloy Ti6Al4V	Titanium Alloy Ti6Al4V	No
Magnet	Neodym Ferrite Boron	Neodym Ferrite Boron	No
Ball	Alpha Sapphire	Alpha Sapphire	Alpha Sapphire
Weight	Tantalum	Tantalum	No
Micro spring	Titanium	No	No
Spring	Titanium Alloy Ti4Al6V	No	Stainless Steel

	New Device Aesculap Miethke M.blue Adjustable Shunt System	Predicate Aesculap Miethke proSA Adjustable Shunt System K161853	Reference Device Aesculap Miethke Shunt System miniNAV Valve K110206
Design:	Circular	Circular	Cylindrical tube
Housing:			
Inner	Smooth	Smooth	Smooth
Outer	Thin curved wave profile	Smooth	Smooth
Audible and tactile feedback	Yes	No	No
Dimensions:			
Height	4.2 mm	4.5 mm	N/A
Diameter	16.6 mm	18 mm	2.8 mm
Length	25.0 mm	27.1 mm	14.7 mm
# of Magnets	4	2	No
Sterilization:	Steam	Steam	Steam
Packaging:	Double Peel Pouch	Double Peel Pouch	Double Peel Pouch
Instruments:			
Compass Adjustment Ring Adjustment Assistant	Manually wipe with an alcohol base cleaner (>75% alcohol). May not be sterilized.	Manually wipe with an alcohol base cleaner (>75% alcohol). May not be sterilized.	N/A
Checkmate	For use in a sterile surgical field. Sterile, reusable, may be re-sterilized	For use in a sterile surgical field. Sterile, reusable, may be re-sterilized	N/A
Instrument settings and readings	0 – 40 cmH_2O	0 – 40 cmH_2O	N/A
Instrument Packaging:			
Instrument set	Leather case	Metal case	N/A
Single Instrument	PE case	PE case	N/A

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 M.blue valve of the Miethke Shunt System performs as intended and is substantially equivalent to the predicate device.

Performance testing was conducted in accordance with EN ISO 7197:2009 standard for shunt safety and performance including the identified stated clauses.

Test	Test Summary	Results
Radiopacity	Shunt identifiable by radiographic pressure coding system via X-ray examination. Visual examination of X-ray images detecting the radiographic pressure coding and flow direction.	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.
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.	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.
Control of the Implanted Shunt	Functionality of the shunt and the method of control	Functional characteristics and control procedure are cited in the Instructions of Use and therefore substantially equivalent to the predicate device.
Pressure-Flow	Pressure-flow-performance tested between the flow range of 5 to 50 ml/h. The measured pressure has to remain inside manufacturer's declaration.	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.
Overpressure	Function and integrity of the subject device shall withstand a positive pressure of 1 m water column applied to the open shunt.	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.
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.	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.
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).	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.
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.	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.

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)	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.
Influence of the changed posture of the patient on the valve performance	The characteristics of the valve depend on the posture of the patient.	The performance characteristics are cited in the Instructions for Use and therefore substantially equivalent to the predicate device.
Accuracy of the M.blue plus Compass	To verify the equivalence between a radiographic verification method and the non-invasive method.	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.
Effects of Exposure to MRI conditions	To verify that the MRI exposure had no effect on the valve function and adjustability.	Samples passed the acceptance criteria and therefore substantially equivalent to the predicate device.
Brake safety test evaluation	To verify that the Active-Lock mechanism protects against inadvertent re-adjustment by external magnetic fields.	There was no change in pressure setting and therefore substantially equivalent to the predicate device.
MRI safety testing	• Image artifacts testing per ASTM F2119 • Radio frequency induced heating testing per ASTM F2182 • Magnetically induced torque testing per ASTM F2213 • Magnetically induced displacement force testing per ASTM F2052	The results demonstrate 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.

The performance testing demonstrates that the device is safe, as effective, and performs as well as or better than the predicate. The minor differences between the M.blue Adjustable Shunt System and the predicate device raise no new issues of safety or effectiveness.

BIOCOMPATIBILITY:

Biocompatibility evaluations were conducted according to International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and Use of International Standard ISO 10993-1, "Biological evaluation of medical devices –l Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff.

Cytotoxicity testing and biological risk assessments were conducted. The materials of the M.blue Adjustable Shunt System are the same as previously cleared Miethke Shunt System submissions (K120559/K161853).

The following biocompatibility testing was submitted in support of substantial equivalence.

M.blue plus with Control reservoir and Peritoneal catheter		
Test	**Test Summary**	**Conclusions**
Cytotoxicity - Extraction Method and XTT Dye	Cell culture treated with test sample exhibited no leachable substances in cytotoxic concentrations released from the test item	Non-Cytotoxic

M.blue plus Compass scale ring		
Test	**Test Summary**	**Conclusions**
Cytotoxicity – Extraction Method and XTT Dye	Cell culture treated with test sample exhibited no substances with cytotoxic potential released from the test item.	Non-Cytotoxic

M. blue Checkmate		
Test	**Test Summary**	**Conclusions**
Cytotoxicity – Extraction Method and XTT Dye	Cell culture treated with test sample exhibited no substances with cytotoxic potential released from the test item.	Non-Cytotoxic

The cytotoxicity testing and biological risk assessments demonstrated that the M. blue valve and M.blue plus Instruments do not pose a risk and are safe for their intended use.

CONCLUSION:

Based on the indications for use, design, materials, function, comparison to the predicate device, and performance testing performed, it can be concluded that the Aesculap Miethke M.blue Adjustable Shunt System is substantially equivalent to the Aesculap Miethke proSA Adjustable Shunt System (K161853).