May 8, 2020

Aesculap, Inc.
Kathy Racosky
Project Manager I
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K200950
Trade/Device Name: Miethke Ventricular Catheter
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG, HCA
Dated: April 9, 2020
Received: April 9, 2020

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., M.S.
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)*
K200950

Device Name
Miethke Ventricular Catheter

Indications for Use *(Describe)*
The catheter 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)**

***Ventricular Catheter***

*April 9, 2020*

**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 Ventricular Catheter

**COMMON NAME**: Shunt, Central nervous System and Components

**CLASSIFICATION:** Class II

**CLASSIFICATION NAME:** Central Nervous System Fluid Shunt and Components Ventricular Catheter

**REGULATION NUMBER:** 882.5550, 882.4100

**PRODUCT CODE:** JXG, HCA

**PREDICATE DEVICE**

- Miethke Shunt System (K020728)

**DEVICE DESCRIPTION**

The ventricular catheter is part of the Miethke Shunt System. It is used to gain access to the cavities of the brain for shunting of excessive CSF.

The ventricular catheter will be offered in lengths of 18 cm or 25 cm with an inner diameter of 1.2 mm and an outer diameter of 2.5 mm. The ventricular catheter contains five stripe depth markers at 3, 5, 7, 10 and 13 cm from the catheter tip. The ventricular catheter is manufactured using barium sulfate filled silicone elastomer.

The purpose of this submission is to seek clearance for modifications to the ventricular catheter which is part of the Miethke Shunt System (K020728). This submission proposes the following modification:

- adding stripe depth markers at 4, 6, 8, 9, 11 and 12 cm and point markers at 1 cm intervals on both sides of the tubing starting at 3.5 cm to 12.5 cm from the catheter tip.

The ventricular catheter is designed to articulate with existing Miethke Shunt Systems, such as the M.blue Adjustable Shunt System, Miethke Shunt System GAV 2.0 and SA 2.0 Valves, proGAV 2.0 Adjustable Shunt System, proSA Progammable Shunt System, Miethke Shunt System miniNAV valve, Miethke Shunt System Gravity Assisted Valve (GAV), and the Miethke Shunt System (DSV, ShuntAssistant, paedi-GAV, connectors, and reservoirs) cleared by FDA (K192266/K190174/K161853/K141687/K120559/K110206/K103003/K062009/K031303/ K030698/K011030).

## INDICATIONS FOR USE

The catheter is used for cerebrospinal fluid (CSF) shunting.

## SUBSTANTIAL EQUIVALENCE and COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The table below provides a summary of the device technological characteristics comparing the ventricular catheter to the predicate device. While the indications for use for the predicate device is slightly different than the proposed device, they both have the same intended use.

| | Aesculap Miethke Shunt System | Ventricular Catheter |
|---|---|---|
| **K#** | Predicate device (K020728) | Proposed device (K200950) |
| **Indications** | The Miethke Shunt system is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum. | The catheter is used for cerebrospinal fluid (CSF) shunting. |
| **Catheter Material** | $BaSO_4$ filled silicone elastomer | Same |
| **Catheter Body Dimensions** | 1.2 mm ID (0.050") x 2.5 mm OD (0.100") | Same |
| **Catheter Length** | 10, 18 and 25 cm | 18 and 25 cm |
| **Catheter Markers** | Numerical w/stripe at 3, 5, 7, 10 & 13 cm | Same<br><br>Stripe at 4, 6, 8, 9 11 & 12 cm<br><br>Dot between 3.5-12.5 cm at 1 cm intervals |
| **Ink markers** | Tantalum powder | Same |
| **Tip Configuration** | Bullet shape with 16 inlet holes (4 rows of 4 holes) | Same |
| **Sterilization** | Steam | Same |

**PERFORMANCE DATA**

Non-clinical laboratory performance testing was conducted in accordance with ASTM F 640-12 standard test methods for determining radiopacity for Medical Use. All samples met predefined acceptance criteria and the proposed device passed design verification test activities. The test results demonstrate that the ventricular catheter performs as intended and is substantially equivalent to the predicate device.

**CONCLUSION:**

The information provided in this submission demonstrates that the modification to the ventricular catheter is substantially equivalent to the marketed predicate device. The minor differences between the ventricular catheter and the predicate device raise no new issues of safety or effectiveness.