December 16, 2024

Aesculap Inc.
Kathy Racosky
Technical Manager II
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K242003
Trade/Device Name: XABO Ventricular Catheter, XABO Peritoneal Catheter, XABO Catheter Set
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: November 15, 2024
Received: November 15, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2024.12.16 10:37:07 -05'00'

Adam D. Pierce, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242003

Device Name

XABO Ventricular Catheter, XABO Peritoneal Catheter, XABO Catheter Set

Indications for Use *(Describe)*

The XABO Catheters 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.

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

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510(k) #: K242003

510(k) Summary

Prepared on: 2024-11-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Aesculap Inc.
Applicant Address	3773 Corporate Parkway Center Valley PA 18034 United States
Applicant Contact Telephone	610-984-7402
Applicant Contact	Kathy Racosky
Applicant Contact Email	kathy.racosky@bbraunusa.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	XABO Ventricular Catheter, XABO Peritoneal Catheter, XABO Catheter Set
Common Name	Central nervous system fluid shunt and components
Classification Name	Shunt, Central Nervous System And Components
Regulation Number	882.5550
Product Code(s)	JXG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K110560	Medtronic ARES Antibiotic- Impregnated Catheters	JXG
K011030/K020728/ K	Aesculap Miethke Shunt System	JXG

Device Description Summary

21 CFR 807.92(a)(4)

The XABO Catheters are manufactured using barium sulfate filled silicone elastomer and are impregnated with clindamycin hydrochloride and rifampicin designed to be released over time from the exterior and inner lumen surface once implanted.

The XABO Ventricular Catheters will be offered in 18 cm or 25 cm in length with an inner diameter of 1.2 mm and an outer diameter of 2.5 mm. Lengths are marked in 1 cm intervals starting from 3 cm to 13 cm from the catheter tip, thus enabling the surgeon to gauge the depth of penetration of the catheter into the lateral ventricle. The proximal end of the catheter has 16 flow holes; four lines of four holes around the catheter circumference.

Components supplied with the XABO Ventricular Catheter include a pre-loaded stainless steel stylet and depending on the configuration may contain a deflector.

The XABO Peritoneal Catheters measure 60 cm, 90 cm or 120 cm in length, 1.2 mm in inner diameter, and 2.5 mm in outer diameter. There are no length markers or wall slits on the catheter, and the tip is open ended. The catheter may be trimmed to the proper length.

The XABO Catheters are 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, Miethke Shunt System miniNAV valve, and the Miethke Shunt System (DSV, connectors, and reservoirs) cleared by FDA (K192266/K190174/K161853/K141687/K110206/K030698/K011030).

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The XABO Catheters are used for cerebrospinal fluid (CSF) shunting.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use is the same as the reference device.

Technological Comparison 21 CFR 807.92(a)(6)

As established in this submission, the XABO Catheters are antibiotic-impregnated catheters offered in similar dimensions, lengths, marker lengths and tip configurations that are substantially equivalent to the predicate and reference device. The subject device is shown to be substantially equivalent and has the same technological characteristics to its predicate devices through comparison in design, function, principles of operation, intended use, material composition, and range of sizes.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance bench testing:

Testing was conducted in accordance with ISO 7197 (2006). Testing results confirm that the XABO Catheters meet performance specifications.

Zone of Inhibition, Drug Content, Drug Release Kinetic and Crush Resistance Comparison testing of the XABO Catheters and the predicate device show that they have the same characteristics.

MRI Safety Testing according to ASTM F2052, ASTM F2213, ASTM F2182 and ASTM FF2119 demonstrated that the deflector is MR Conditional in 3-Tesla Magnetic Resonance Imaging systems per ASTM F2503.

All testing was performed on the worst-case final finished device.

Biocompatibility testing:

A biocompatibility evaluation was conducted in accordance with ISO 10993-1 and "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process", as recognized by FDA. Biocompatibility testing included Cytotoxicity, Sensitization, Intracutaneous Irritation/Reactivity, Genotoxicity, Implantation, Acute Systemic Toxicity, Sub- Chronic, Hemolysis, and Pyrogenicity. Chronic systemic toxicity and carcinogenicity endpoints have been addressed by a chemical characterization (extractable and leachable studies).

A toxicological risk assessment evaluated the risk of chronic systemic toxicity, carcinogenicity, and developmental and reproductive toxicity to patients associated with exposure to the extractable compounds to adult, pediatric an dneonatal patients.

The XABO Catheters and deflector are considered an implant device, tissue/bone contact device of permanent duration (>30 days). While the stylet is classified as indirect contact in the area of tissue/bone intended for less than 1 hour duration.

Conclusion:
Results of all testing confirm that the XABO Catheters as a component of a shunt system meet the acceptance criteria for the specified shelf life, conform to applicable standard ISO 7179, and are equivalent in function to the predicate device, the Medtronic ARES Antibiotic-Impregnated Catheters.

Results of the conducted comparative performance testing confirm that the performance characteristics for both devices, the XABO Catheters and Medtronic ARES Antibiotic-Impregnated Catheters, are substantial equivalent.