August 20, 2024

Borvo Medical, Inc.
Ming Cheng Chew
Regulatory Consultant
2500 Old Middlefield Way, Suite E
Mountain View, California 94043

Re: K241458
Trade/Device Name: Borvo EVAC System (Ergo); Borvo EVAC System (Classic)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: May 22, 2024
Received: May 23, 2024

Dear Ming Cheng Chew:

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.

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: 2024.08.20 14:37:29 -04'00'

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.

510(k) Number *(if known)*
K241458

Device Name
Borvo EVAC System (Ergo);
Borvo EVAC System (Classic)

Indications for Use *(Describe)*
The EVAC is indicated to facilitate the evacuation of a chronic or subacute hematoma or hygroma in the cranium. The EVAC is intended for draining of fluid accumulated in the subdural space, including chronic or subacute hematomas and hygromas. The EVAC is also intended for removing air and fluid from the subdural space following open surgical procedures to remove subdural collections.

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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1 510(k) Summary: K241458

1.1 Contact Information

Sponsor/Manufacturer
Borvo Medical Inc.
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Correspondent
Ming Cheng Chew
Regulatory Consultant,
RQM+
Phone: 763-232-3701
Email: mchew@rqmplus.com

Date: August 20, 2024

1.2 Device Information

Name of Device:	Borvo EVAC System
Classification Name:	Central Nervous System Fluid Shunt and Components
Regulation Number:	21 CFR 882.5550
Regulatory Class:	II
Product Code:	JXG

1.3 Predicate Device

Medtronic SEPS Cranial Access Kit (K042359)

1.4 Device Description

The Borvo EVAC System is intended for the drainage of subdural fluid accumulations. The EVAC System is designed to gradually drain fluid to an external reservoir by creating a low negative pressure in the subdural space. It consists of 3 components:

1. EVAC Port (Ergo or Classic)
2. Tubing
3. Vacuum bulb

An optional Cranial Access Kit can be purchased with the EVAC System, or a commercially available Cranial Access Kit with a 5.31mm drill bit can be used.

1.5 INDICATIONS FOR USE

The EVAC is indicated to facilitate the evacuation of a chronic or subacute hematoma or hygroma in the cranium. The EVAC is intended for draining of fluid accumulated in the subdural space, including chronic or subacute hematomas and hygromas. The EVAC is also intended for removing air and fluid from the subdural space following open surgical procedures to remove subdural collections.

1.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1-1: Device Comparison to the Predicate Device

Characteristic	Borvo EVAC System	Medtronic SEPS Cranial Access Kit (K042349)
Intended Use	Intended for the for drainage of subdural fluid accumulations.	Same
Indication for Use	The EVAC is indicated to facilitate the evacuation of a chronic or subacute hematoma or hygroma in the cranium. The EVAC, is intended for draining of fluid accumulated in the subdural space, including chronic or subacute hematomas and hygromas. The EVAC is also intended for removing air and fluid from the subdural space following open surgical procedures to remove subdural collections	Use of the SEPS Cranial Access Kit is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The SEPS Cranial Access Kit is intended for drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir. The SEPS Cranial Access Kit is also intended for draining air and fluids from the subdural space immediately following craniotomy procedures performed to remove a chronic or subacute subdural hematoma.
Product Code	JXG	Same
Regulation	21 CFR 882.5550	Same
Components	Port	Same

Characteristic	Borvo EVAC System	Medtronic SEPS Cranial Access Kit (K042349)
	Tubing Vacuum Bulb Cranial Access Kit	
Drill Bit Compatibility	5.31 mm	Same
Port Material	Titanium	Stainless Steel
Port ID Distal	0.150 inches	0.149 inches
Port ID Proximal	0.160 inches	0.149 inches
Port OD at threads	0.241 inches	0.236 inches
Port OD at barbs	0.250 inches	0.236 inches
Thread pitch	0.75 mm	0.75 mm
Port Wing Configuration	Angular (Classic) or Curvilinear (Ergo)	Angular
Tubing Material	Thermoplastic Elastomer	Silicone
Bulb Configuration	Jackson-Pratt Reservoir	Same
Sterile	Yes	Same
Single-use only	Yes	Same
Biocompatibility	ISO 10993-1	Same

1.7 PERFORMANCE DATA

A high-level summary of the testing conducted to confirm the safety and efficacy of the Borvo EVAC System is as follows:

- Dimensional
- Tensile
- Pull-Out Force
- Simulated Use
- Sterile Barrier/Packaging Testing
- Shelf Life
- Biocompatibility

1.8 SUBSTANTIAL EQUIVALENCE

Based on the same intended use, similar technological characteristics, and the summary of data submitted, the Borvo EVAC System is found to be substantially equivalent to the predicate device. Testing demonstrated the device safety and effectiveness as intended without raising new and different questions of safety and effectiveness.