June 14, 2018

Aqueduct Critical Care, Inc.
Thomas Clement
President & CEO
11822 North Creek Parkway North, Suite 110
Bothell, Washington 98011

Re: K181301
Trade/Device Name: Smart External Drain (SED) System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG, GWM
Dated: May 16, 2018
Received: May 17, 2018

Dear Thomas Clement:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181301

Device Name
Smart External Drain (SED) System

Indications for Use *(Describe)*

Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:

- Reduce intracranial pressure (ICP), e.g., pre-, intra- or postoperative.
- Monitor CSF chemistry, cytology, and physiology.
- Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

Monitoring of intracranial pressure (ICP) is indicated in selected patients with:

- Severe head injury
- Subarachnoid hemorrhage graded III, IV, or V preoperatively
- Reye's syndrome or similar encephalopathies
- Hydrocephalus
- Intracranial hemorrhage
- Miscellaneous problems when drainage is to be used as a therapeutic maneuver

Monitoring can also be used to evaluate the status pre- and postoperatively for space-occupying lesions.

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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510(k) Summary

General Information:

Date of Summary Preparation:	May 16, 2018
Name and Address of Manufacturer:	Aqueduct Critical Care, Inc. 11822 North Creek Parkway North Suite 110 Bothell, WA 98011
Contact Person:	Tom Clement, President and CEO Phone: 425-985-1571 Fax: 425-278-9377
Trade Name:	Smart External Drain (SED) System
Common Name:	External CSF Drainage System
Regulation Number:	Primary: § 21 CFR 882.5550 Secondary: § 21 CFR 882.1620
Regulation Description:	Central Nervous System Fluid Shunt and Components Intracranial Pressure Monitoring Device
Regulatory Class:	Class II
Classification Panel:	Neurology
Product Code:	Primary: JXG Secondary: GWM

Device Description: The SED System is based upon traditional gravity-based drainage systems, but is designed to allow for the automated regulation of ICP (in Ventricular mode) or regulation of drainage (in Lumbar mode) without the need for continuous manual measurements, adjustments and interventions. The SED System consists of an electromechanical software embedded SED Console and a sterile, disposable SED Cartridge, which includes all components necessary to attach to the external drainage catheter via a luer-lock connector and to a drainage bag that collects the drained fluid.

The SED System is mounted on an IV pole, with the SED Console positioned by the user at an easy-to-view height, while the drainage bag is positioned below the lowest possible patient head position, which is considered to be below the height of a hospital bed.

The SED System automatically maintains a set drainage rate (for lumbar use) or set ICP (for ventricular use) using a drip counter or pressure sensors (transducers), respectively, and an automated stepper-motor pinching mechanism that compresses or releases the system's compliant drain tubing in order to control the degree of CSF flow (i.e., equivalent to the alteration of CSF flow that happens when a traditional gravity drain is manually raised or lowered). The SED System displays the measured drainage or ICP information, while additionally incorporating multiple alarms provided by its automated functionality.

The SED System can thus automatically compensate for patient movement, allow for greater mobility (via a battery backup) and also alert hospital staff if the ICP and/or drainage values exceed the set maximum or minimum levels for a particular patient.

The modifications included under this Special 510(k) include the following:

- Changed the Low Drain Alarm reactivation from 10 minutes to 60 minutes in the Ventricular Mode when the SED Cartridge has been confirmed to be properly primed
- Added user prompts to the User Interface Screen to provide a user check that the drain tubing path within the SED Cartridge is properly primed prior to use

Indications for Use: Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:

- Reduce intracranial pressure (ICP), e.g., pre-, intra- or postoperative.
- Monitor CSF chemistry, cytology, and physiology.
- Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

Monitoring of intracranial pressure (ICP) is indicated in selected patients with:

- Severe head injury
- Subarachnoid hemorrhage graded III, IV, or V preoperatively
- Reye's syndrome or similar encephalopathies
- Hydrocephalus

- Intracranial hemorrhage
- Miscellaneous problems when drainage is to be used as a therapeutic maneuver

Monitoring can also be used to evaluate the status pre- and postoperatively for space-occupying lesions.

Predicate Device: Aqueduct Critical Care, Inc. cites the following as the predicate device that is being modified.

Predicate Device	Smart External Drain (SED) System	K172759

Table 1 below provides a summary of the technological characteristics of the SED System in comparison to the predicate device.

Table 1: Comparative Summary of the Modified SED System and Predicate SED System

Detail or Technological Characteristic	Modified Aqueduct Critical Care, Inc. SED System	Predicate Aqueduct Critical Care, Inc. SED System (K172759)
Device Trade Name	Same as predicate SED System	Smart External Drain (SED) System
Intended Use	Same as predicate SED System	To attach to an implanted, external drainage catheter in order to externally drain cerebrospinal fluid (CSF) and monitor both CSF drainage for both Lumbar and Ventricular modes and intracranial pressure (ICP) for Ventricular mode.
Attaches to Separate, Commercially Available EVD Catheter	Same as predicate SED System	Yes
Sterile Disposable Tubing Set	Same as predicate SED System	Yes
CSF Drainage Bag	Same as predicate SED System	Yes
Gravity Drainage of CSF	Same as predicate SED System	Yes
Method to Control Gravity Drainage of CSF	Same as predicate SED System *(in both Lumbar and Ventricular modes)*	Automated adjustment based on user settings via a stepper-motor controlled, tube-pinching mechanism to either compress or release the compliant drainage tubing contained within the sterile, disposable SED Cartridge.
Pressure Transducer for ICP Measurement	Same as predicate SED System *(in Ventricular mode)*	Yes
Software-based, Powered Console for User Interface, User ICP, drainage output and Alarm Setting Adjustments, Data Display, and Alarms for ICP and drainage output Monitoring	Same as predicate SED System (*The modified SED System now also incorporates additional user prompts)*	Yes
Method to Account for Location of Ventricles via Patient Head Position	Same as predicate SED System *(in Ventricular mode)*	Reference shroud attached to patient behind the ear (at the level of the EAM) to account for patient's head positioning.
Measured Ventricular Pressure Range	Same as predicate SED System *(in Ventricular mode)*	-5 to 40 cm H_2O (set ICP range)
Measured Lumbar Drainage Output Range	Same as predicate SED System *(in Lumbar mode)*	0 to 45 ml/hr
Displayed ICP	Same as predicate SED System *(in Ventricular mode)*	Yes *(via SED Console display)*
Battery Back-up	Same as predicate SED system	Yes

Testing Summary: To demonstrate intended device performance, as well as to support the substantial equivalence of the modified SED System to the predicate SED System. The performance and technological characteristics were evaluated by completion of the following testing:

- Software Verification and Validation

The results from these testing activities:

- demonstrate that the technological and performance characteristics of the modified SED System are comparable to the predicate SED System, and
- ensure the modified SED System can perform in a manner equivalent to the predicate SED System with the same intended use.

Conclusion (Statement of Equivalence): The information and summary of testing presented within this submission supports a determination of substantial equivalence, and therefore market clearance of the modified SED System via this Special 510(k).