November 14, 2017

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

Re: K172759
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: September 12, 2017
Received: September 13, 2017

Dear Mr. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Carlos L. Pena -S

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)*
K172759

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY - K172759

General Information:

Date of Summary Preparation:	September 12, 2017
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 Monitor
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 or CSF drainage volume 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 or lumbar puncture site, 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 far greater mobility (via a battery backup) and also alert hospital staff if the ICP exceeds the set maximum or minimum levels for a particular ventricular patient, as well as if low or high CSF drainage values are ever exceeded for a particular lumbar patient.

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 devices.

Primary Predicate	Smart External Drain (SED) System	K171586
Secondary Predicate	Duet External Drainage and Monitoring System	K984053

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

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

Detail or Technological Characteristic	**Modified Aqueduct Critical Care, Inc. SED System**	**Primary Predicate Aqueduct Critical Care, Inc. SED System *(NOTE: as presented in K161605 relative to original predicate Duet System)***	**Original K161605 Predicate Medtronic Duet External Drainage and Monitoring System (Secondary Predicate)**
Device Trade Name	Smart External Drain (SED) System	Smart External Drain (SED) System	Medtronic DUET™ External Drainage and Monitoring System
Intended Use	Same	Same	To attach to an implanted, external drainage catheter to externally drain cerebrospinal fluid (CSF) and monitor both CSF drainage and intracranial pressure (ICP).
Attaches to separate, commercially available EVD Catheter	Yes	Yes	Yes
Sterile Disposable tubing set	Yes	Yes	Yes
CSF Drainage Bag	Yes	Yes	Yes
Gravity drainage of CSF	Yes	Yes	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.	Manual adjustment of the drip chamber either up or down the IV Pole, relative to the patient's head position and ventricular catheter location.
Pressure Transducer for ICP Measurement	Same as predicate SED System (*in Ventricular Mode*)	Yes	Yes *(The Duet System includes a design and instructions for attaching a transducer that allows for ICP measurement and visual display via a connected monitor.)*
Software-based, Powered Console for User Interface, User Settings and Alarm Adjustments, Data Storage and Display, and Alarms for ICP Monitoring	Yes	Yes	No *(A transducer can be attached [see above] and then used in conjunction with an ICP Monitor to provide a display and user interface for ICP monitoring.)*
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 (External Auditory Meatus) to account for patient's head positioning.	Laser level must be attached to the system and leveled and then the system "zeroed"; adjustment thereafter may be needed.
Measured Pressure Range	Same as predicate SED System (*in Ventricular Mode*)	-5 to 40 cm H_2O (set ICP range)	0 – 31 cm H_2O (set ICP range)
Measured Lumbar Drainage Rate Range	0 to 45 ml/hr	Not applicable	Controlled by manual adjustment and measured by user over time.
Displayed ICP	Same as predicate SED System (*in Ventricular Mode*)	Yes *(via SED Console display)*	Yes *(via drip chamber pressure indicator window or via connected transducer to patient monitor display)*
Battery Back-up	Same as predicate SED System	Yes	No *(Manual, non-powered system)*

Testing Summary: The subject changes to the SED System have no impact on the device's biocompatibility, electrical safety, packaging, sterilization or shelf life. Therefore, to demonstrate intended device performance, as well as to support the substantial equivalence of the subject SED System, other technological and performance characteristics were evaluated as summarized in Table 2 that follows.

Table 2: Summary Table for Modified SED System Testing

Testing	Testing Summary	Results/Conclusions
SED Cartridge Performance Testing		
Functional Testing of the SED Lumbar Cartridge	SED Lumbar Cartridges were tested as part of the SED System to show that requirements for functionality and the ability of the devices to accurately measure and control the lumbar drainage output were met.	**PASS –** All requirements verified.
SED System Performance Testing		
Supplemental Verification of the Modified SED Cartridge, Console, and System	SED Lumbar Cartridges and an SED Console were evaluated to demonstrate that the devices met the supplemental requirements applicable to the modified device.	**PASS** – All supplemental system requirements verified.
Long-Term (14-Day) Stability of Modified SED System	Modified SED Systems were tested under clinical-use simulation for a period of 14 continuous days (to match the longest expected use duration of the SED System for lumbar drainage).	**PASS** – Modified SED System met all requirements under clinical-use simulation.
Verification of the Drainage Range of the Modified SED System	SED Lumbar Cartridges were tested on SED Consoles to test the extremes of the drainage setting range and drainage accuracy of the system	**PASS** – Modified SED System functioned as intended and met all requirements.
Software Testing		
Software Verification and Validation	Code verification and software verification and validation testing was performed.	**PASS –** Modified SED System met all acceptance criteria for software verification and validation
Electrical Safety and Electromagnetic Compatibility Testing		
Verify the Electromagnetic Compatibility (EMC) of the Modified SED System	Applicable EMC testing (including emissions and immunity) was completed on the modified SED System in accordance with the following standards. • IEC 60601-1-2 Edition 3: 2007-03	**PASS** – Modified SED System met all applicable EMC requirements.

The results from these testing activities:

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

Conclusion (Statement of Equivalence): The data and information presented within this submission support a determination of substantial equivalence, and therefore market clearance of the modified SED System via this 510(k) Premarket Notification.