DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 27, 2016

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

Re: K161605
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
Dated: September 23, 2016
Received: September 26, 2016

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161605

Device Name
Smart External Drain (SED) System

Indications for Use *(Describe)*
Draining and monitoring of CSF flow from the lateral ventricles 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:	October 21, 2016
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 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 ventricular 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 ICP using pressure sensors (transducers) 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 ICP information and also calculates and displays CSF flow volume output, while additionally incorporating multiple alarms given 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 ever the ICP exceeds the set maximum or minimum levels for a particular patient, as well as if low or high CSF drainage values (as also set by the user) are ever exceeded.

Indications for Use: Draining and monitoring of CSF flow from the lateral ventricles 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.

Predicate Device	Duet External Drainage and Monitoring System	K984053

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 SED System and Predicate Duet System

Detail or Technological Characteristic	Subject Aqueduct Critical Care, Inc. SED System	Predicate Medtronic Duet External Drainage and Monitoring System
Device Trade Name	Smart External Drain (SED) System	Medtronic DUET™ External Drainage and Monitoring System
Intended Use	Same	To attach to an implanted, external drainage catheter in order to externally drain cerebrospinal fluid (CSF) and monitor both CSF drainage and intracranial pressure (ICP)
Attaches to separate, commercially available EVD Catheter	Yes	Yes
Sterile Disposable tubing set	Yes	Yes
CSF Drainage Bag	Yes	Yes
Gravity drainage of CSF	Yes	Yes
Method to control gravity drainage of CSF	Automated adjustment based on user settings (for max/min ICP) 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	Yes *(The SED System integrates transducers into its design for drain line and reference line pressure measurements that are used to calculate and regulate ICP.)*	Yes *(The Duet System includes both a design and instructions for attachment of a transducer to the main system stopcock that then allows for measurement and visual display of ICP via a connected monitor.)*
Software-based, Powered Console for User Interface, User ICP and Alarm Setting Adjustments, Data Storage and Display, and Alarms for ICP Monitoring	Yes	No *(Note, however, that 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	Reference shroud attached to patient behind the ear (at the level of the EMA) to account for patient's head positioning.	Laser level must be attached to the system and leveled appropriately and then the system "zeroed"; adjustment thereafter may be needed.
Measured Pressure Range	-5 to 40 cm H_2O (set ICP range)	0 – 31 cm H_2O (set ICP range)
Displayed ICP	Yes *(via SED Console display)*	Yes *(via drip chamber pressure indicator window or via connected transducer to patient monitor display)*
Battery Back-up	Yes	No *(Manual, non-powered system)*

Testing Summary: To demonstrate intended device performance, as well as to support the substantial equivalence of the subject SED System, the technological and performance characteristics were evaluated as summarized in Table 2 that follows.

The results from these testing activities:

- demonstrate that the technological and performance characteristics of the subject SED System are comparable to the predicate external drainage management system, and
- ensure the SED System can perform in a manner equivalent to the predicate device 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 subject SED System via this 510(k) Premarket Notification.

Table 2: Summary Table for SED System Testing

Testing	Testing Summary	Results/Conclusions
SED Console Performance Testing		
SED Console Verification	Simulated use test cases completed with all requirements tested to verify SED Console performance.	**PASS – A**ll requirements verified.
SED Cartridge Performance Testing		
SED Cartridge Pinch Tubing Force and Fatigue	SED Cartridges were tested to show that the pinch tubing met requirements, including resistance to pinch tubing fatigue and shut off / pinch force.	**PASS –** All requirements verified.
SED Cartridge Button Verification	SED Cartridges were tested to show that the manual pinch button on the cartridge met the following requirements: activation force, leak resistance, and fatigue life.	**PASS** – All requirements verified.
MRI Compatibility	The SED Cartridge was tested in an MRI environment of 1.5-Tesla and 3.0-Tesla.	**PASS** – All requirements verified.
Tubing Kink and Crush Verification	SED Cartridges were tested in a bend radius to assess kink resistance. For crush resistance, fluid flow exhibited no change when a force was applied to the tubing compared to no force applied.	**PASS** – All requirements verified.
Dimensional Verification	SED Cartridges were dimensionally measured.	**PASS** – Measurements confirmed that all dimensional requirements were met.
Drainage Bag Verification	SED Cartridges were tested to show that drainage bags met requirements for: capacity, venting, and wetting.	**PASS** – All requirements verified.
Bond Joint Testing	SED Cartridges were used to destructively pull test the bond joint configurations.	**PASS** – All bond joints met or exceeded the minimum pull strength specification.
SED System Performance Testing		
SED System Mechanical Verification	The SED System was tested to ensure that all applicable mechanical requirements were met.	**PASS** – The SED Console was shown to function properly following the maximum anticipated number of latching and unlatching cycles.
Verification of SED System Environmental Conditions	The SED System was subjected to the extremes of the specified environmental conditions (including temperature, humidity, and altitude) to confirm intended system functionality post-conditioning.	**PASS** – SED System functioned as intended post-conditioning.
Long-Term Stability of SED System	SED Systems were tested under clinical-use simulation for the longest expected use duration of the SED System.	**PASS** – SED System met all requirements under clinical-use simulation.

Testing	Testing Summary	Results/Conclusions
Verification of the Pressure Measurement Range and Response Time of the SED System	The SED System was tested to the extremes of the pressure measurement range, as well as to measure the response time of the system.	**PASS** – All applicable requirements verified.
Packaging Validation Testing		
Packaging Validation Testing	The packaging configurations for the reusable SED Console and sterile SED Cartridge and Drain Bag were subjected to applicable distribution simulation per ASTM D4169, followed by testing: The SED Console was tested to ensure it maintained proper function via simulated clinical-use. The sterile SED Cartridge and Drain Bag packaging was subjected to seal strength, dye leak testing, and visual inspection, while the SED Cartridge and Drain Bag were subjected to functional testing to confirm proper device function.	**PASS** – Package integrity and product functionality met all applicable requirements.
Sterilization Validation Testing		
Sterilization Validation	Sterilization validation testing was completed to validate that the gamma radiation (min 25 kGy) sterilization process provides a Sterility Assurance Level (SAL) of 10^{-6}, using the following applicable standards and sterilization validation methods. • AAMI / ANSI / ISO 11737-1:2006 (R) 2011 • AAMI / ANSI / ISO 11737-2:2009/(R) 2014 • AAMI / ANSI / ISO 11137-1:2006/(R) 2010, [Including: Amendment 1 (2013)] • AAMI / ANSI / ISO 11137-2:2013	**PASS** – The gamma radiation sterilization process provides an SAL of 10^{-6}.
Shelf-Life Testing		
Shelf-Life Testing	Accelerated age testing was completed on the SED Cartridge and SED Drain bag components and their respective packaging to support a 6-month shelf life.	**PASS** – All packaging and functional requirements were met following 6 months of accelerated aging.

Testing	Testing Summary	Results/Conclusions
Biocompatibility Testing		
Biocompatibility Testing	Biocompatibility testing completed on all direct (skin) and indirect (potential limited and brief periods of retrograde drainage fluid flow) contact portions of the SED System. This included cytotoxicity, sensitization, intracutaneous reactivity, LAL pyrogenicity and acute systemic toxicity.	**PASS** – SED System met all applicable biocompatibility requirements for its intended use.
Software Testing		
Software Verification and Validation	Code verification and software verification and validation testing was performed.	**PASS –** SED System met all acceptance criteria for verification and validation
Electrical Safety and Electromagnetic Compatibility Testing		
Verify the Electrical Safety and Electromagnetic Compatibility (EMC) of the SED System	Applicable electrical safety and EMC testing (including emissions and immunity) was completed on the SED System in accordance with the following standards. • AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) (IEC 60601-1:2005, MOD) • IEC 60601-1-2 Edition 3: 2007-03 • IEC 60601-1-8 Edition 2.0 2006-10	**PASS** – SED System met all applicable electrical safety and EMC requirements.