May 18, 2018

Branchpoint Technologies, Inc.
Nicholas Hu
Chief Operating Officer
Contact Address

Re: K172209
Trade/Device Name: AURA ICP Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: April 19, 2018
Received: August 25, 2017

Dear Nicholas Hu:

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,

Michael J. Hoffmann -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)*
K172209

Device Name
AURA™ ICP Monitoring System

Indications for Use *(Describe)*
The Branchpoint AURA™ ICP Monitoring System is intended for use by a qualified neurosurgeon in the direct monitoring of intracranial pressure in intraparenchymal applications.

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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K172209
510(k) Summary

Submitter Information

Company Name:	Branchpoint Technologies, Inc.
Contact Person:	Nicholas Hu
Address:	1 Technology Drive, Suite I-811, Irvine, CA 92618
Telephone Number:	(949) 829-1868
Date Prepared:	May 18th, 2018

Subject Device

Trade Name:	AURA™ ICP Monitoring System
Common or Usual Name:	Intracranial Pressure Monitor
Classification:	Class II, Intracranial Pressure Monitoring Device 21 CFR 882.1620
Product Code:	GWM

Predicate Device

Primary Predicate:	Camino Slim Line ™ System K042728 21 CFR 882.1620, GWM

Device Description

The Branchpoint AURA™ ICP Monitoring System is a device intended for monitoring intracranial pressure (ICP). The Branchpoint AURA™ ICP Monitoring System is composed of the following three packages:

Package 1) AURA™ Sensor Tray (Model SP101-A)

- AURA™ Sensor (Model I0025G)
- Disposable Scalp Retractor (Model OS0001B)
- Disposable Drill Bit with Collar (Model I0008C)
- Disposable Torque Wrench (Model OS0004C)
- Disposable Antenna Holster (Model I0007A)

Package 2) AURA™ Monitor Pack (Model TK101-A)

- AURA™ Monitor (Model T0011B)
- AURA™ Antenna (Model T0010A)
- 2x Lithium-Ion 11v Rechargeable Batteries (Model T0032A)
- Two-bay battery charger (Model T0014A)

Package 3) AURA™ Data Receiver Pack (Model DG101-A)

- AURA™ Data Receiver (Model D0004B)

Package 1 of The Branchpoint AURA™ ICP Monitoring System is comprised of components which are described below, all of which are intended for SINGLE-USE ONLY:

AURA™ Sensor (Model I0025G)

The AURA™ Sensor is a strain gage pressure sensor that is placed at the standard location for ICP monitoring (Kocher's Point). The AURA™ Sensor is placed using the same procedure as predicate

ICP monitors. The AURA™ Sensor has a catheter tip that extends into the parenchyma of the brain. The AURA™ Sensor does not contain a battery or power storage capacitor. It receives power inductively from the AURA™ Monitor (Model T0011B) through the AURA™ Antenna (Model T0010A). The exclusion of internal power storage in the AURA™ Sensor eliminates risks associated with batteries. The AURA™ Sensor is provided sterile (ethylene oxide) as part of the AURA™ Sensor Tray (Model SP101-A).

The AURA™ Sensor measures ICP and relays the data to the handheld AURA™ Monitor. The AURA™ Monitor is the primary user interface and displays a numerical ICP value on its screen. Optionally, the AURA™ Monitor also relays the ICP data to the AURA™ Data Receiver, which outputs the ICP waveform to standard patient bedside monitors.

Drill Bit with Collar (Model I0008C)
The drill bit with collar is used to drill the burr hole for the AURA™ Sensor. This is a class I device with product code HTW that is exempt from premarket notification per 21 CFR 888.4540 and is currently legally marketed in the United States. The drill bit has a diameter of 6.3 mm and has an adjustable collar to be used to help ensure proper drilling depth. The collar has a set-screw that can be adjusted by the user with the torque wrench for loosening and tightening. The drill bit and collar are manufactured from medical grade stainless steel (DIN 1.4021).

Torque Wrench (Model OS0004C)
The torque wrench allows the user to loosen and tighten the collar on the drill bit to limit the drilling depth. This is a class I device with product code HXC that is exempt from premarket notification per 21 CFR 888.4540 and is currently legally marketed in the United States. It is made of nickel plated chromium vanadium (DIN 1.4305).

Scalp Retractor (Model OS0001B)
The scalp retractor is a skin retractor that can be used during the placement of the AURA™ Sensor. This is a class I device with product code GAD that is exempt from premarket notification per 21 CFR 878.4800 and is currently legally marketed in the United States. It is constructed from medical grade stainless steel (DIN 1.4301, 1.4305 and 1.4021).

Antenna Holster (Model I0007A)
The antenna holster is designed to hold an AURA™ Antenna securely in place over an AURA™ Sensor in all possible positions. It is made of thermoplastic elastomer and affixes to the skin with an adhesive (hydrocolloid).

Package 2 of The Branchpoint AURA™ ICP Monitoring System is comprised of components which are described below:

AURA™ Monitor Pack (Model TK101-A)
The AURA™ Monitor Pack is provided non-sterile. The AURA™ Monitor (Model T0011B) handheld is the primary user interface device that connects to an AURA™ Antenna (Model T0010A). The AURA™ Antenna powers and receives ICP data streamed from the AURA™ Sensor. The AURA™ Monitor handheld controller displays numerical ICP on its screen. Optionally, the AURA™ Monitor can relay the ICP data to a nearby AURA™ Data Receiver. The AURA™ Monitor uses an externally replaceable lithium-ion battery pack that can be recharged in the charger provided in the AURA™

Monitor Pack (Model TK101-A). A fully-charged battery is capable of running the AURA™ Monitor for at least 8 hours. **These devices are intended for reuse**.

Package 3 of The Branchpoint AURA™ ICP Monitoring System is comprised of components which are described below:

AURA™ Data Receiver Pack (DG101-A)

The AURA™ Data Receiver Pack is provided non-sterile. The AURA™ Data Receiver receives ICP waveform data relayed by the AURA™ Monitor and outputs them to existing 3rd party patient monitors. The AURA™ Data Receiver plugs directly into the patient monitor's invasive blood pressure port, a port that is governed by AAMI BP22: 1994 (R) 2011 Blood Pressure Transducers (FDA recognition number 3-44). There are various 3rd party adapter cables currently available on the market that will allow the AURA™ Data Receiver to connect to various 3rd party patient monitors and the AAMI BP22 standard ensures compatibility across different brands and models. The AURA™ Data Receiver does not contain a battery and does not need to be recharged; it is able to run from the excitation voltage provided by the invasive blood pressure port. **The AURA™ Data Receiver is intended for reuse.**

Intended Use

The Branchpoint AURA™ ICP Monitoring System is intended for use by a qualified neurosurgeon in the direct monitoring of intracranial pressure in intraparenchymal applications.

Comparison of Technological Characteristics & Intended Use to Predicate Device

The table below presents a summary of the technological characteristics of the AURA™ ICP Monitoring System in comparison to the predicate device. The indications for use for the predicate device is similar to the indications for use for the AURA™ ICP Monitoring System. There are no major technological differences between the AURA™ ICP Monitoring System and predicate systems that raise new issues of safety or effectiveness. Thus, the AURA™ ICP Monitoring System is substantially equivalent to the predicate devices.

Characteristic	**AURA™ ICP Monitoring System K172209 Subject Device**	**Camino Slim Line ™ System K042728 Predicate Device**
Measured Variable	ICP	ICP and intracranial temperature
Clinical Application	Parenchymal pressure measurement	Parenchymal and sub-dural pressure and temperature measurement
Mechanism for ICP measurement	Solid state pressure sensor for direct measurement	Solid state pressure sensor for direct measurement
Classification Regulation	21 CFR § 882.1620	21 CFR § 882.1620
Classification Name (Product Code)	GWM	GWM
Intended Use	For use by a qualified neurosurgeon in the direct monitoring of intracranial pressure in intraparenchymal applications.	For use by a qualified neurosurgeon in the direct monitoring of intracranial pressure in both sub-dural and intraparenchymal applications.
Catheter Construction	Polyurethane	Polyurethane

Characteristic	AURA™ ICP Monitoring System K172209 Subject Device	Camino Slim Line ™ System K042728 Predicate Device
Catheter Dimensions	2.5cm long x 2mm diameter	10cm long x 1.35 diameter
Calibration Method	Stored calibration values in ICP sensor.	Stored calibration values in ICP sensor and manual zeroing.
Display Variables	ICP digital display and waveform	ICP digital display and waveform
Measurement Units for ICP	ICP in mmHg	ICP in mmHg
Sensor Connection to Monitor	Data: Bluetooth low energy (range = 7 m for monitor handheld and data receiver) Power: Inductive coupling (range = 1.5 cm for monitor antenna)	Direct, percutaneous cable connection
Sensor Power Source	Powered by monitor	Powered by monitor
Monitor Power Source	Battery	Battery or mains
Sterilization	Ethylene oxide (single use)	Ethylene oxide (single use)
Monitoring Duration	<30 Days	< 30 Days
Surgical Technique	Skin incision and burr hole	Skin incision and burr hole

Non-Clinical Testing in Support of Substantial Equivalence and Device Performance

The following bench testing was conducted to support a determination of substantial equivalence to the predicate and to demonstrate performance. The non-clinical bench tests included:

- ICP Monitor performance testing prescribed by ANSI/AAMI NS28:1988(r)2010;
- Pressure measurement resolution testing;
- Barometric pressure compensation testing;
- System response time testing;
- Battery and charger performance testing;
- Electrical safety testing;
- Electromagnetic compatibility testing;
- Wireless power testing;
- Wireless data transmission testing;
- Wireless co-existence testing;
- Immunity to RFID testing;
- Specific absorption rate (SAR) simulation testing;
- Device mechanical integrity testing;
- Hardware reliability testing;
- Device insulation performance testing;
- Vibration and shock testing;
- Device operating temperature testing;
- Adhesion performance testing;
- Device environmental exposure testing;

- Labeling durability testing;
- System usability testing;
- Audio and alarm tone testing;
- Software testing;
- Sterilization validation testing; and
- Shelf-life and packaging testing.

The non-clinical testing demonstrates that the AURA™ ICP Monitoring System meets pre-defined acceptance criteria and is as safe and effective as predicate devices.

Biocompatibility Testing

All patient contacting components of the AURA™ ICP Monitoring System were evaluated for biocompatibility. The type and nature of the patient contact for each of these components and their biocompatibility testing results are summarized below.

The AURA™ Sensor is placed subcutaneously above the skull and contacts bone and tissue, with the potential to contact cerebrospinal fluid. The contact duration of the AURA™ Sensor is expected to be over 24 hours and under 30 days. Biocompatibility testing was conducted on all patient contacting components of this device, which included the encapsulation, enclosure and catheter. The study results and conclusions for these tests are summarized below:

Test	Results
MEM Elution ISO 10993-5	**Non-cytotoxic:** score of 0.
Sensitization Maximization Extract ISO 10993-10	**Non-sensitizer:** No irritation was found on any of the negative control or test animals.
Intracutaneous Reactivity ISO 10993-10	**Non-Irritant:** The test device score for both extracts was 0.
Acute Systemic Injection ISO 10993-11	**No systemic toxicity:** No test or control animals exhibited signs of toxicity.
Subacute and Subchronic Toxicity (IV) ISO 10993-11	**No systemic toxicity:** No systemic toxic effects were observed.
Subacute and Subchronic Toxicity (IP) ISO 10993-11	**No systemic toxicity:** No systemic toxic effects were observed.
Genotoxicity – Ames ISO 10993-3	**Non-mutagenic:** The test article did not cause an increase in revertant colonies for any strain greater than two-fold over negative control values.
Genotoxicity – Mutagenicity ISO 10993-3	**Non-clastogenic & non-genotoxic:** No statistical significant differences ($p \geq 0.05$) were noted between the test and control extracts.
Genotoxicity – Mouse Lymphoma ISO 10993-3	**Non-mutagenic & non-clastogenic:** RTG was > 10%.
Subcutaneous Implantation ISO 10993-6	**No systemic toxicity:** Macroscopic reaction of the test article was not significant as compared to control. Microscopically, test article is classified as a slight irritant as compared to control.

Test	Results
Brain Tissue Implantation ISO 10993-6	**No systemic toxicity:** Neurobehavioral, gross pathological and clinical reactions caused by the test article were not significant as compared to control. Histologically, test article is classified as having minimal or no reaction.
Mediated Material Pyrogenicity ISO 10993-11	**Non pyrogenic:** Temperature increase was < 0.5 °C for all animals.
Indirect (extract) Hemolysis ISO 10993-4 ASTM F756-17	**Non hemolytic:** Test article hemolytic index was 0.00%.

The Disposable Antenna Holster is placed on the scalp and contacts intact skin. The contact duration of the Disposable Antenna Holster is expected to be over 24 hours and under 30 days. Biocompatibility testing was conducted on the adhesive layer, which is the only patient contacting component. The study results and conclusions for these tests are summarized below:

Test	Result
MEM Extraction Cytotoxicity ISO 10993-5	**Non-cytotoxic:** score of 0.
Skin Irritation ISO 10993-10	**No irritation:** irritation index was 0.
Closed Patch Sensitization ISO 10993-10	**No sensitization:** no contact sensitization observed.

The collective results of the biocompatibility testing demonstrate that the AURA™ ICP Monitoring System meets established specifications and is biocompatible.

Conclusion

The body of testing summarized above indicates that the AURA™ ICP Monitoring System performs as intended and is substantially equivalent to predict devices. It is as safe and effective as the identified predicate.

Conformance to Standards

Standards to which the AURA™ ICP Monitoring System conforms are outlined below:

Body	Standard ID	Standard Title	FDA Recognition #
AAMI ANSI ISO	10993-1 2009/(R)2013	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process	2-156
AAMI ANSI ISO	10993-3 2014	Biological Evaluation Of Medical Devices - Part 3: Tests For Genotoxicity, Carcinogenicity And Reproductive Toxicity	2-226
AAMI ANSI ISO	10993-5 2009(R)2014	Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	2-153

Body	Standard ID	Standard Title	FDA Recognition #
AAMI ANSI ISO	10993-6 2007/(R)2014	Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation	2-120
AAMI ANSI ISO	10993-7 2008(R)2012	Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	14-278
AAMI ANSI ISO	10993-10 2010/(R)2014	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	2-173
AAMI ANSI ISO	10993-11 2006/(R)2010	Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity	2-118
AAMI ANSI ISO	11135 2014	Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices	14-479
AAMI ANSI ISO	11607-1 2006/(R)2010	Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]	14-457
AAMI ANSI ISO	14161 2009/(R)2014	Sterilization Of Health Care Products - Biological Indicators: Guidance For The Selection, Use And Interpretation Of Results	14-285
ISO	14708-1 2014	Implants for surgery -- Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	N/A; Not Recognized
AAMI ANSI ISO	14971 2007/(R)2010	Medical Devices - Applications Of Risk Management To Medical Devices	5-70
AAMI ANSI ISO	15223-1 2012	Medical Devices - Symbols To Be Used With Medical Devices Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements	5-91
IEC	60068-2-27 2008	Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	N/A; Not Recognized
AAMI ANSI ES	60601-1 2005/(R)2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)	19-4
AAMI ANSI IEC	60601-1-2 2007/(R)2012	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance Collateral Standard: Electromagnetic Compatibility - Requirements And Tests	19-2

Body	Standard ID	Standard Title	FDA Recognition #
AAMI ANSI IEC	60601-1-2 2014	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests	19-12
AIM	7351731	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard	19-21
IEC	60601-1-6 Edition 3.1 2013-10	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability	5-89
AAMI ANSI IEC	60601-1-8 2006 & A1:2012	Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems	5-92
IEC TR	60878 Ed. 3.0 B:2015	Graphical Symbols For Electrical Equipment In Medical Practice	5-104
AAMI ANSI IEC	62304 2006	Medical Device Software - Software Life Cycle Processes	13-32
AAMI ANSI IEC	62366 2007/(R)2013	Medical Devices - Application Of Usability Engineering To Medical Devices	5-67
AAMI ANSI	BP22 1994/(R)2011	Blood Pressure Transducers	3-44
ASTM	D4169-16	Standard Practice For Performance Testing Of Shipping Containers And Systems	14-499
ASTM	F1886/F1886M-09	Standard Test Method For Determining Integrity Of Seals For Flexible Packaging By Visual Inspection	14-288
ASTM	F1980-16	Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices	14-497
ASTM	F2096-11	Standard Test Method For Detecting Gross Leaks In Packaging By Internal Pressurization (Bubble Test)	14-359
ASTM	F88/F88M-15	Standard Test Method For Seal Strength Of Flexible Barrier Materials	14-482
ISTA	2A 2016)	International Safe Transit Association, ISTA 2 Series: Partial simulation performance tests, packaged products weighing 150 lbs. or less	N/A; Not Recognized
AAMI	NS28 1988/(R)2010	Intracranial Pressure Monitoring Devices	17-1
AAMI ANSI	ST72 2011/(R)2016	Bacterial Endotoxins – Test Methods, Routine Monitoring, And Alternatives To Batch Testing	14-360