February 4, 2024

Integra LifeSciences Production Corporation
Kali Sacco
Manager, Regulatory Affairs
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K232890
Trade/Device Name: CereLink ICP Monitor (826820), CereLink ICP Extension Cable (826845)
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: January 5, 2024
Received: January 5, 2024

Dear Kali Sacco:

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,

Jay R. Gupta -S

Jay Gupta
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232890

Device Name
CereLink ICP Monitor (826820);
CereLink ICP Extension Cable (826845)

Indications for Use *(Describe)*
The ICP Monitor is intended for use as an interface between compatible strain gauge type pressure transducers and standard physiological pressure monitoring systems. The ICP Monitor is also intended for use as an independent pressure monitor for displaying the mean, systolic and diastolic values of a physiologic pressure waveform in the absence of an external patient monitor. The CereLink ICP Extension cable is intended for use as a connecting cable between the ICP input channel of the CereLink ICP Monitor and a CereLink ICP Sensor.

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

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a) (1) Submitter Information	
Name and Address	Integra LifeSciences Production Corporation 11 Cabot Boulevard Mansfield, MA 02048
Telephone number	(680) 910-4999
Primary Contact	Kali Sacco
Date Summary Prepared	January 31, 2024
807.92(a) (2) Name of Device	
Trade or Proprietary Name	CereLink® ICP Monitor (826820) and CereLink ICP Extension Cable (826845)
Common Name	Intracranial Pressure Monitoring System
Classification Name	Device, Monitoring, Intracranial Pressure (21 CFR 882.1620)
Device Class	II
Product Code	GWM
807.92(a) (3) Predicate Information	
Predicate Device	CereLink ICP Monitor and CereLink ICP Extension Cable K210993 Product Code: GWM
807.92(a) (4) Device Description	
The CereLink ICP Monitor is indicated for use in the ICU or Operating Room (OR) environment for monitoring intracranial pressure (ICP) via a solid-state sensor placed directly in parenchymal tissue or integrated into an external ventricular drainage catheter placed in the ventricle. In addition to monitoring ICP and activating alarms when the intracranial pressure is outside user-set limits, the device performs these functions:	

- Displays ICP Waveform
- Displays Mean ICP numeric
- Displays the historic mean pressure as a trend
- Displays trend statistics (Pressure Time Dosage (PTD), time above threshold, boxplot, histogram)
- Stores 14-days' worth of mean ICP values
- Stores 24 hours of pressure waveform
- Can capture and store screen-shots
- Can download various data to a USB device for printing or analysis
- Real-time data streaming of mean ICP and waveform via USB connection
- Connect to external patient monitor

The CereLink ICP Monitor can be transported with the patient within the hospital to continuously record data. The monitor includes a 7" color touch screen that is compatible with the use of gloves. The monitor is provided to the user with a CereLink ICP Extension Cable, external power supply, and comes equipped with an internal rechargeable battery. The monitor has one output channel to transfer physiological data to a compatible Patient Monitor, as well as one input channel to receive ICP readings from the implanted CereLink ICP sensor. The implanted sensor is connected to the CereLink ICP Monitor by way of the CereLink ICP Extension Cable; the CereLink ICP Monitor connects to compatible patient monitors through the patient monitor interface cables.

807.92(a) (5) Indications for Use

The CereLink ICP Monitor is intended for use as an interface between compatible strain gauge type pressure transducers and standard physiological intracranial pressure monitoring systems. The CereLink ICP Monitor is also intended for use as an independent intracranial pressure monitor for displaying the mean, systolic and diastolic values of a physiologic pressure waveform in the absence of an external patient monitor. The CereLink ICP Extension cable is intended for use as a connecting cable between the ICP input channel of the CereLink ICP Monitor and a CereLink ICP Sensor.

807.92(a) (6) Technological Characteristics Compared to Predicate

The CereLink ICP Monitor is identical to the predicate CereLink ICP Monitor with the identical intended use, indications for use, clinical utility, design, features, user interface and fundamental scientific technology.

The CereLink ICP Extension Cable has the same intended use, indications for use, clinical utility, and fundamental scientific technology as the predicate CereLink ICP Monitor and CereLink ICP Extension Cable. In comparison to the predicate, the proposed CereLink ICP Monitor and CereLink ICP Extension Cable include the following modifications:

CereLink ICP Extension Cable – Addition of Patient Lead. The addition of the electrically isolated patient lead is to provide electrical equilibrium between the patient and CereLink system's isolated circuits, preventing a "DC Negative Offset".

- A Y-connection will be added near the distal end of the CereLink ICP Extension Cable.
- One leg of the Y-connection will be the existing (unmodified) distal end of the cable that connects to the ICP sensor. The other leg of the Y-connection will add an electrically isolated patient lead with a pinch connector that is compatible with standard ECG electrodes

CereLink ICP Monitor and CereLink ICP Extension Cable Instructions for Use - Labelling changes are the result of the CereLink ICP Extension Cable changes proposed in this submission

- Describe how to use the patient lead with a pinch connector,
- Add a precaution regarding the patient lead with pinch connector's impact on reliable performance of the ICP sensor,
- Include additional details for cable and cord management, and
- Add troubleshooting steps addressing out of range failure and usage of the patient lead

CereLink ICP Monitor Package labels - Package label was updated to identify all contents within the package.

CereLink ICP Monitor and CereLink ICP Extension Cable package configuration - CereLink ICP Extension Cable will be packaged separately from the CereLink ICP Monitor unit box. It will be

provided to the customer within the same shipping container as the CereLink Monitor for customer convenience.

807.92(b) 1-2: Summary of Nonclinical and Clinical Testing Performed

The following performance testing has been conducted in support of the substantial equivalence determination. All testing was performed on production equivalent devices. Results of verification and validation testing conducted on the CereLink ICP Monitor and CereLink ICP Extension Cable demonstrate that the device performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device.

To reproduce the conditions that lead to the CereLink out-of-range errors, an in-vitro platform was developed and has been named the "electrical stress setup." The electrical stress setup simulates the external factors and elements that leads the CereLink system into the Out-of-Range state. The external factors are electrical and chemical in nature, and all must be present at a sufficient level to reproduce the failure.

The Electrical Stress Setup can consistently reproduce the Out-of-Range failures at a significantly higher rate than the failures seen in the clinical setting, allowing the setup to be used as part of design verification to demonstrate the reliability and effectiveness of the CereLink ICP Extension Cable design change. The Electrical Stress Setup was used as part of ICP Drift Test and Out of Range Failure Test.
In the ICP Drift Test, the CereLink Systems were exposed to the Electrical Stress Setup, with the ICP Extension Cable Patient Lead correctly connected. During 30 days of continuous testing, the ICP drift was found to meet the specification.

In the Out-of-Range Test, the CereLink Systems were exposed to the Electrical Stress Setup, with the ICP Extension Cable Patient Lead connected incorrectly. As expected, all CereLink Systems were induced in to the out-of-range failure within the specified time. The ICP Extension Cable Patient Lead was then connected correctly, and the test demonstrated that all CereLink Systems recovered from the failure within the specified amount of time.

Based on the testing performed as summarized, the CereLink ICP Monitor with the proposed changes to the CereLink ICP Extension Cable does not raise new questions of safety or effectiveness and supports substantial equivalence to the predicate device.

Performance Bench Test Results	
Test	**Conclusion**
Mechanical Tests	Pass
Electrical Testing (Impedance Measurement)	Pass
Out of Range Failure Test *Utilized the electrical stress setup	Pass
30 Day ICP Drift Test *Utilized the electrical stress setup	Pass
Mean Time Between Failure Calculation Test	Pass
Simulated Environment Validation Test (13 days)	Pass
Label Verification Test	Pass
Drawing Verification Test	Pass
Summative Usability Report	Pass

Biocompatibility Testing Results	
Test	**Conclusion**
ISO 10993-5:2009	Pass
ISO 10993-10:2021	Pass
ISO 10993-23:2021	Pass

Electrical Safety and Electromagnetic Compatibility Test Results	
Test	**Conclusion**
IEC 60601-1: 2005+AMD1:2012+AMD2:2020	Pass
IEC 60601-1-6: 2010+AMD1:2013+AMD2:2020	Pass
IEC 60601-1-8:2006+AMD1:2012+AMD2:2020	Pass
IEC 60601-1-2:2014+AMD1:2020	Pass
IEC 62366-1:2015+AMD1:2020	Pass

Animal Studies

No animal studies were required. Verification and validation of the subject devices was achieved based on the comparison to the predicate devices and from the results of the bench, biocompatibility, electrical safety, and electromagnetic compatibility testing.

Clinical Studies
No clinical studies were required. Verification and validation of the subject devices was achieved based on the comparison to the predicate device and from the results of the bench, biocompatibility, electrical safety, and electromagnetic compatibility testing.
807.92(b) (3) Conclusion
Based upon the intended use, design, operating principle, scientific technology and comparison to the predicate device, and testing performed, it is concluded that the proposed modifications to the CereLink ICP Monitor and CereLink ICP Extension Cable do not raise any new questions of safety and effectiveness, and are therefore, substantially equivalent to the predicate, CereLink ICP Monitor and CereLink ICP Extension Cable.