April 30, 2021

Integra LifeSciences Production Corporation
Marybeth Carson
Regulatory Affairs Specialist
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K210993
Trade/Device Name: CereLink ICP Monitor
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: April 1, 2021
Received: April 2, 2021

Dear Marybeth Carson:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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 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)*
K210993

Device Name
CereLink ICP Monitor

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.

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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Integra CereLink ICP Monitor
510(k) Summary

(1) Submitter Information	
Name	Integra LifeSciences Production Corporation
Address	11 Cabot Boulevard Mansfield, MA 02048
Telephone number	(781) 971-5600
Primary Contact	MaryBeth Carson
Date of Submission	April 1, 2021
(2) Name of Device	
Trade or Proprietary Name	CereLink® ICP Monitor
Common Name	Intracranial Pressure Monitoring System
Classification Name	Intracranial Pressure Monitoring Device (21 CFR 882.1620)
Device Class	II
Product Code	GWM
Rx or OTC Designation	Rx Only
(3) Predicate Information	
Predicate Device	CereLink ICP Monitor: K183406
Reference Device	Codman ICP Express: K945585

(4) Device Description

The CereLink ICP Monitor is indicated for use in the ICU or 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 an 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 (cleared via K173192). The implanted sensor is connected to the CereLink ICP Monitor by way of the CereLink ICP Extension Cable (cleared via K183406); the CereLink ICP Monitor connects to compatible patient monitors through the patient monitor interface cables (cleared via K152670).

There are no changes to the currently marketed CereLink ICP sensors, CereLink ICP Extension Cable, or the patient monitor interface cables due to the CereLink ICP Monitor modifications.

(5) Intended Use of Device

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.

(6) Technological Characteristics Compared to Predicate

The CereLink ICP Monitor remains substantially equivalent to the predicate CereLink ICP Monitor. The CereLink ICP Monitor has the same intended use, indications for use, clinical utility, design principles, features, user interface and fundamental scientific technology as the predicate CereLink ICP Monitor. In comparison to the predicate, the proposed CereLink ICP Monitor includes the following modifications:

Component Affected	Proposed Modification	Rationale
Power Supply	<u>External Power Supply:</u> • Replace the current 2-pronged (pin) floating power supply for a 3-pronged power supply: this new power supply continues to be Class II but now includes a functional earth connection. The DC output cable is the same length, but now has 2 conductors surrounded by a shield	• The change to a grounded power supply is made to substantially reduce the high common mode noise that affects ICP sensor performance. The reference device, Codman ICP Express, (K945585) uses a grounded power supply.

	connected to earth ground via a choke. • Addition of a 330uH choke to the power supply between earth ground and the shield. • There is a slight increase in the power supply cable diameter from 4.5mm to 5.4mm. There is no change on the dimensions of the brick itself.	• The addition of the choke improves immunity to electrical fast transients and allows the device to meet the electromagnetic compatibility requirements. • The addition of a second conductor within the shield increases the diameter of output cable while protecting the lines from external disturbances and signal coupling.
	<u>Cord to Outlet Connection:</u> • Replace the power supply blade to outlet connection with a power supply cord to outlet connection. • Changes length from 4m to 6.5m	Power supply is provided with a cord connection to outlet rather than blade. This increases the total length of the power supply from 4m to 6.5m, due to the 2.5m of the cord connection.
Internal Modifications	Removal of 2 capacitors of analog board	The capacitors are no longer needed in the board design as a result of the proposed changes
	Addition of a resistor to the Extension Cable input circuit	The resistor was added for grounding, better shielding and to reduce common mode noise
	• Replace DC/DC converter to one with 2 means of patient protection.	These changes were made to reduce leakage current and

	• Replace and/or remove multiple isolation capacitors on digital board.	ensure 2 means of patient protection.
	Replaced metal standoffs with nylon spacers, washers and cup sleeves to separate analog board from digital board	The changes were made to increase creepage and clearance distances
	Added ferrite to battery charger circuit of the digital board.	Ferrite was added to reduce radiated emissions for EMC requirements.
	Added conductive copper tape to electrically connect the LCD back plate to the grounded metal frame.	The copper tape electrically connects the LCD back plate to the metal frame, thereby grounding the LCD, providing a path to ground for electrostatic discharges, as part of EMC requirements.
Back Housing of the CereLink ICP Monitor	Increased size of retention mechanism used to hold power supply cable.	The new power supply cable is slightly thicker and would not fit in original back housing retention mechanism.
Software Updates	Software updates to correct anomalies.	The software updates were made to correct anomalies observed in the field.
	Added a digital Processor watchdog.	This watchdog triggers a reboot of both the digital and analog processors if the monitor becomes unresponsive for 80 seconds. The monitor will then continue normal operation without user intervention.

		Implemented to control electrical fast transient effects.
	A software check was enabled to monitor USB Babble interruptions.	The software monitors the frequency of babble interruptions due to EFT pulses; device enters failsafe state if error conditions met. Unit will reboot within 2 minutes to resume normal operation without user intervention. Implemented to control electrical fast transient effects.
Packaging	Increased the size of the carton containing the power supply and altered the foam inserts within the overall CereLink ICP Monitor unit box.	The size of the power supply carton was increased to accommodate the new power supply due to the increase in diameter of the DC output cord; the foam inserts within the CereLink ICP Monitor unit box were modified accordingly to package the larger power supply carton and power supply cord.
Labelling	Updates made to address the changes described above and FDA recognized symbols.	Labelling changes are the results of changes proposed in this submission and to include the latest recognized symbols per FDA consensus standards.

Summary of Nonclinical and Clinical Testing Performed

The following performance, software, electrical safety, and electromagnetic compatibility testing has been conducted in support of the substantial equivalence determination. The testing utilized well-established methods, including test methods seen in the predicate CereLink ICP Monitor 510(k): K183406.

Results of verification and validation testing conducted on the CereLink ICP Monitor demonstrated that the proposed device performed as designed, is suitable for its intended use and is substantially equivalent to the predicate device.

Performance Testing Results	
Test	**Conclusion**
ICP Drift Test	Pass
Common Mode Noise and Leakage Current Power Supply Test	Pass
Mean Time Between Failure Calculation Test	Pass
Drop Test	Pass
Patient Monitor Related Test	Pass
Patient Sensor Related Test	Pass
13 Day Simulated Environment Validation Test	Pass
Sensor and Monitor Compatibility Testing	Pass
Electrical Testing	Pass

Software Test Results	
Test	**Conclusion**
Software Validation Fail Safe Test	Pass
Software Functional Test	Pass
Software Code Review	Pass
Software Unit Test	Pass
Software Acceptance Test	Pass
Label and GUI Review	Pass

Electrical Safety and Electromagnetic Compatibility Results	
Test	**Conclusion**
IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007 + A1:2012	Pass
IEC 60601-1-6:2010 + A1:2013	Pass
IEC 60601-1-8:2006 + A1:2012	Pass
IEC 60601-1-2:2014	Pass

Sterilization/Cleaning

The CereLink ICP Monitor is provided non-sterile. There are no changes to any sterilization or cleaning parameters of the subject device.

Shelf-Life Testing

The CereLink ICP Monitor is a reusable, non-sterile device. Therefore, there is no expiry date and shelf-life is not applicable for this device.

Biocompatibility Testing

The CereLink ICP Monitor is non-patient contacting. Therefore, biocompatibility is not applicable for this device.

Animal Studies

No animal studies were required. Appropriate verification and validation of the subject device was achieved based on the comparison to the predicate device and from the results of the bench, software, electrical safety, and electromagnetic compatibility testing.

Clinical Studies

No clinical studies were required. Appropriate verification and validation of the subject device was achieved based on the comparison to the predicate device and from the results of the bench, software, electrical safety, and electromagnetic compatibility testing.

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 do not raise any new questions of safety and effectiveness, and is therefore, substantially equivalent to the predicate, CereLink ICP Monitor.