K183406 – 510(k) Summary

I. Submitter

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II. Device

Device Proprietary Name	CereLink ICP Monitor
Common Name	Intracranial Pressure Monitoring System
Classification Name	Intracranial Pressure Monitoring Devices (21 CFR 882.1620)
Regulatory Classification	II
Product Code	GWM
Rx or OTC Designation	Rx Only

III. Predicate & Reference Devices

The predicate and reference devices for this submission are:

	510(k) Number	Date Cleared	Title
Predicate Device	K945585	October 26, 1995	CU-II (Codman ICP Express)
Reference Device	K152670	January 22, 2016	DirectLink Extension Cable and Patient Monitor Interface Cables

IV. Device Description

The CereLink ICP Monitor is intended 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 mean pressure values
- Displays the pressure waveform
- Displays the historic mean pressure as a trend

- Displays trend statistics (Area Under the Curve (AUC), 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

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 sold with an 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 ICP sensor. The implanted sensor is connected to the CereLink ICP Monitor by way of the CereLink ICP Extension Cable (code 82-6845).

The CereLink ICP Monitor and CereLink ICP Extension Cable are intended to be used in conjunction with Codman's other neuromonitoring devices: the CereLink ICP Sensor Kits (codes 82-6850, 82-6851, 82-6852, and 82-6854 cleared via K173192) and the patient monitor interface cables (codes 82-6880, 82-6881, and 82-6882 cleared via K152670). The CereLink ICP Sensor converts the patients intracranial pressure to a voltage signal. The monitor provides power to the sensor, interprets the voltage signal from the sensor, and displays the corresponding pressure measurements taken by the sensor during a patient's treatment and during patient transport. There is no change to the currently marketed CereLink ICP Sensor Kits or the patient monitor interface cables as a result of the monitor modifications described in this submission.

V. Indications for Use

The table below describes the Indications for Use statements for the proposed CereLink ICP Monitor product codes.

CereLink ICP Monitor and Extension Cable Indications for Use		
Device Description	**Proposed Product Code**	**Proposed Indications for Use**
CereLink ICP Monitor	82-6820	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.
CereLink ICP Extension Cable	82-6845	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.

VI. Comparison to Predicate Device

The CereLink ICP Monitor is substantially equivalent to the predicate device, the Codman ICP Express, and is eligible for the Special 510(k) process, as the proposed device has the following similarities to the predicate device:

- the same intended use,
- the same indications for use,
- the same clinical utility,
- the same patient population,
- the same fundamental scientific technology (analog front end input compatible with the same ICP Sensors, analog back end output compatible with external patient monitors, pressure signal digitalization for mean ICP calculation and an algorithm to detect an implanted sensor to avoid re-zeroing), and
- incorporates the same basic design (small profile, light weight, ideal for monitoring patients during transport)

The differences between the predicate and subject device are intended to enhance the user interface of the device, and to improve ease of use and accuracy. With the addition of the color touch-screen, users are able to review additional data directly on the CereLink ICP Monitor without the need to connect to an additional patient monitoring system.

The table below provides a comparison between the subject device and the predicate device.

To Table Comparison of the Predicate and Subject Device			
	Predicate Device: Codman ICP Express (K945585)	**Subject Device: CereLink ICP Monitor (This Submission)**	**Discussion**
FDA Regulatory Information			
Manufacturer	Codman & Shurtleff, Inc.	Same as predicate	n/a
FDA Product Code	GWM	Same as predicate	n/a
Classification	21 CFR 882.1620	Same as predicate	n/a
Classification Name	Device, Monitoring, Intracranial Pressure	Same as predicate	n/a
Indications			
Indications for Use	The ICP Express is intended for use as an interface between compatible strain gauge type pressure transducers and standard physiological pressure monitoring systems. The ICP Express is also intended for use as an independent pressure monitor for displaying the mean, systolic and diastolic **numeric** values of a physiologic pressure waveform in the absence of an external patient monitor.	Same as predicate*	*The word "numeric" was removed from the Indications from Use statement. The systolic and diastolic numeric values on the ICP Express were necessary to show waveform pulsatility (i.e., waveform presence). The CereLink ICP Monitor provides the user with a modernized graphical user interface, where the ICP waveform is displayed and pulsatility can be easily assessed, rather than using a digital number reading. This minor change to the Indications for Use statement does not change the overall Indications for Use statement or intent.
Intended Use	Monitor: Intended to serve as an interface between the implanted ICP pressure sensor and compatible patient monitoring systems. Extension Cable: Intended for use as a connecting cable between the ICP input channel of the ICP monitor and an implanted ICP pressure sensor.	Same as predicate	n/a
Basic Device Design			
Reusable	Yes	Same as predicate	n/a
Operating Range	-50 to 250 mmHg	-50 to 150 mmHg	Pressure values above 150mmHg are not physiological. Reducing the overall pressure range allows for accuracy improvements.

Input Pressure Channel/ Output Pressure Accuracy	+/- 1% of reading or 1 mmHg, whichever is larger (exclusive of sensor)	+/- 0.5 mmHg over the range -50 to 50 mmHg and +/- 1% over the range 50 to 150 mmHg (exclusive of sensor)	Better accuracy from -50 to 50 mmHg and the same accuracy from 50 to 150 mmHg.
Method of Operation	Strain gauge technology to read the pressure sensor	Same as predicate	n/a
Monitor Features	LCD Display Continuous numeric display of the mean, systolic and diastolic ICP Must connect to patient monitor for detailed waveform analysis High and Low Alarms Rechargeable Battery to use during transport	LCD Display with touch screen On-screen ICP waveform (systolic and diastolic), Mean ICP numeric display, mean ICP trend and trend statistics (AUC, time above threshold, histogram, boxplot) Can connect to patient monitor to display the ICP Waveform (optional) High and Low Alarms Rechargeable Battery to use during transport Stores 14-days' worth of patient data Can capture and store screen-shots Can download various data to a USB device for analysis and printing	Graphical user interface modifications are being made to modernize the device and provide greater flexibility to the users
Materials	Non-patient contacting	Same as predicate	n/a
External Patient Monitor Interface	Excitation Voltage Range: 0.5 to 10VDC or VAC Sensitivity: 5 or 40uV/Vex/mmHg	Excitation Voltage Range: 0 to 6.5VDC Sensitivity: 5uV/Vex/mmHg	Most patient monitors in the market have an excitation voltage range of 5VDC and sensitivity of 5uV/Vex/mmHg. Limiting the specifications has no impact on the use of the device.
Supply Voltage	120 VAC	85-240 VAC	The wider ranging supply voltage allows users world-wide to use the same CereLink Monitor
Supply Frequency	50/60 Hz	Same as predicate	n/a
AC Powered	Yes	Same as predicate	n/a
Rechargeable Battery Powered	Yes	Same as predicate	n/a
Electrical Safety Testing	IEC 60601-1 IEC 60601-1-2	Same as predicate	n/a

Sterility	Non-Sterile	Same as predicate	n/a
Cleaning	Wipe external surface with 70% isopropyl alcohol or mild hospital cleaning detergent/bactericide	Wipe external surface with 70% isopropyl alcohol or a combination wipe consisting of quaternary ammonium and isopropyl alcohol	The combination wipes used for cleaning the proposed device are consistent with the mild hospital cleaning detergent/bactericide commonly found in the hospital setting.
Reprocessing	The ICP Express Extension Cable cannot be sterilized	The CereLink ICP Extension Cable can be sterilized in an autoclave steam sterilizer if required by the hospital	The CereLink ICP Extension Cable is almost identical to the reference device, the DirectLink Monitor Extension cable (K152670). The CereLink ICP Extension cable and the DirectLink Monitor Extension Cable can be sterilized in an autoclave steam sterilizer if required by the hospital.
ICP Monitor Accessories and For-Use-With Devices			
Compatible ICP Sensors	Microsensors: 626631US 626632US 626638US 626633US 626653US CereLink Semsors: 826850 826851 826852 826854	CereLink Sensors 826850 826851 826852 826854	The CereLink ICP Sensors, 82 series family, has been cleared by the FDA via K173192. The CereLink sensors contain a memory PCB that stores the sensor's zero value when used with the proposed CereLink ICP Monitor. With this function, sensors can now be disconnected and reconnected from the ICP monitor without having to re-enter the zero value. The Microsensor, 62 series family is not compatible with the CereLink ICP Monitor because it does not include the memory PCB.
Compatible Patient Monitor Interface Cables	ICP Express Patient Monitor Interface Cables: 826645 826646 826647	CereLink Patient Monitor Interface Cables: 826880 826881 826882	The CereLink Patient Monitor Interface Cables are identical to the reference device, the Direct Link Monitor Interface cables (K152670). The CereLink ICP Monitor cable output was designed specifically to be identical to the cable output on the DirectLink device. No modifications to the cable were required.
Included Accessories	ICP Extension Cable, & Power Supply	Similar to predicate	Similar in design and serve the same purpose as those packaged with the predicate ICP Express accessories. CereLink power supply uses an external AC to DC converter, while the power supply for ICP Express is internal to the device.
Replacement Accessories for Purchase	ICP Extension Cable, Replacement Battery, Replacement Power Supply	Similar to predicate	Similar in design and serve the same purpose as predicate ICP Express accessories. CereLink power supply uses an external AC to DC converter, while the power supply for ICP Express is internal to the device. Both devices use Li-Ion rechargeable batteries.

VII. Performance Data

The following performance testing has been conducted in support of the substantial equivalence determination. All testing was performed on production equivalent devices unless otherwise specified.

Bench Testing

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

Performance Bench Test Results		
Test	**Test Method Summary**	**Results**
Mechanical Performance Testing	The purpose of this test is to verify the mechanical specifications defined in the Codman CereLink ICP Monitor System Requirements Specification. There are three test elements included: Mechanical Inspection, Mechanical Measurement, and Mechanical Demonstration Test Analysis.	All results passed, demonstrating substantial equivalence of the proposed device.
Ingress Protection Test	This test serves to subject the CereLink ICP Monitor against ingress of liquid and solid materials as per IEC60529:2004 to an IP22 rating.	All results passed, demonstrating substantial equivalence of the proposed device.
Drop Testing	This test serves to verify that the Codman CereLink ICP Monitor meets the requirements for drop testing specified within IEC 60601-1 section: 15.3.4.2.	All results passed, demonstrating substantial equivalence of the proposed device.
Audible and Visual Indicators	This test is to verify that all alerts and alarm indicators volume and frequency, as well as visual indicators, exist and function as required.	All results passed, demonstrating substantial equivalence of the proposed device.
Extension Cable Testing	This test is to verify that the ICP Extension Cable can transfer ICP signals from the sensor to the monitor as required.	All results passed, demonstrating substantial equivalence of the proposed device.
Electrical Performance Testing	This test is to verify the electrical specifications are as specified by design of the CereLink ICP Monitor: • Power adaptor output voltage and current • Battery operational time • Automatic diagnostic tests • Datasheet parameters related to electrical specifications • SD storage card specifications	All results passed, demonstrating substantial equivalence of the proposed device.
Patient Sensor Testing	This test is to verify the functionality of the interface of the system with the ICP pressure sensor.	All results passed, demonstrating substantial equivalence of the proposed device.
Patient Monitor Related Tests	This test is to verify the functionality of the interface of the system with external patient monitors.	All results passed, demonstrating substantial equivalence of the proposed device.

Device Reliability and Mean Time Between Failure Calculation	This test serves to verify the devices expected service life for the CereLink ICP Monitor device.	No samples were required for execution of this test. Analysis on materials and components have been deemed to meet the use and service life claim. This demonstrates substantial equivalence of the proposed device.
Environmental Testing	This test is to verify that specified temperature, humidity and pressure do not impact the performance and physical state of the CereLink ICP Monitor.	All results passed, demonstrating substantial equivalence of the proposed device.
Summative Usability Testing	This test provides documentation that the CereLink ICP Monitor meets clinician requirements and expectations to operate the system as intended, safely and effectively.	All results passed, demonstrating substantial equivalence of the proposed device.
System Validation Testing	This test is to verify that the CereLink ICP Monitor can be used in conjunction with the ICP Microsensor probe, pressure simulator and patient bedside monitor. The CereLink monitor can calibrate the pressure simulator or the ICP Microsensor Probe which will then be used to generate signals that correspond to intracranial pressure. Pressure readings will be displayed on a patient bedside monitor and on the CereLink Monitor. Intracranial Pressure (ICP) reading shall be consistent among different CereLink Monitors and common Patient Bedside Monitors when using different interface cables.	All results passed, demonstrating substantial equivalence of the proposed device.
Transit Testing	Testing was performed on final finished devices, including accessories sold separately, showing that shipping did not impact package integrity and therefore the packaging of the devices are capable of maintaining device integrity.	All results passed, demonstrating substantial equivalence of the proposed device.

Software Testing

Software testing was conducted in accordance with FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* issued May 11, 2005. Results of verification and validation testing conducted on the CereLink ICP Monitor demonstrated that the proposed device performed as designed, is suitable for the intended use, and is substantially equivalent to the predicate device.

Software Test Results	
Test	**Conclusion**
Software Unit Testing	Pass
Software Code Review	Pass
Software Functional Testing	Pass
Graphical User Interface Review	Pass
Failsafe Testing	Pass

Electrical Safety and Electromagnetic Compatibility Testing

The CereLink ICP Monitor design is compliant for Electrical Safety and EMC per IEC 60601-1 3rd and IEC 60601-1-2 4th edition. The CereLink ICP Sensor Kits, ICP Extension Cable, Patient Monitor Interface Cables, Power Supply and Battery are listed as applied parts within the CereLink ICP Monitor safety reports and documentation.

Electrical Test Results	
Test	**Conclusion**
IEC 60601-1:2005/A1:2012, Edition 3	Pass
IEC 60601-1-2:2014, Edition 4	Pass
IEC 60601-1-8:2006, Edition 2	Pass
IEC 60601-1-6:2010	Pass
IEC 62366:2007	Pass
IEC 62304:2006/AMD1:2015	Pass

Sterilization/Cleaning

The CereLink ICP Monitor and accessories are non-sterile capital equipment and not intended to be sterilized. Therefore, sterilization is not applicable for these devices. A validation was performed to support cleaning instructions in the device labeling (Instructions for Use) in accordance with FDA's Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* issued March 17, 2015.

The CereLink ICP Monitor and accessories can be cleaned using 70% isopropyl alcohol or using a combination wipe consisting of Quaternary Ammonium and Isopropyl Alcohol, which is commonly available in the hospital setting. A wipe-down reliability test was conducted and demonstrated passing results.

If required by the hospital, the CereLink ICP Extension Cable can be sterilized in an autoclave steam sterilizer using the parameters provided in the CereLink ICP Extension Cable Instructions for Use.

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 these devices.

Animal Studies
No animal studies were required as 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, and electrical/safety testing.

Clinical Studies
No clinical studies were required as 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, and electrical/safety testing.

VIII. Conclusion

Based upon the intended use, design, operating principles, fundamental scientific technology, comparison to the predicate device, and testing conducted, it is concluded that the CereLink ICP Monitor is substantially equivalent to the predicate device, the Codman ICP Express, and therefore does not raise any new issues of safety and effectiveness.