November 8, 2017

Codman & Shurtleff, Inc
Megan Palumbo
Regulatory Affairs Project Lead
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K173192
Trade/Device Name: CereLink ICP Sensor Basic Kit (82-6850), CereLink ICP Sensor Metal Skull (82-6851), CereLink ICP Sensor Plastic Skull (82-6852), CereLink ICP Sensor Ventricular Catheter Kit (82-6854)
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: September 29, 2017
Received: October 2, 2017

Dear Ms. Palumbo:

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)*
K173192

Device Name
CereLink ICP Sensor Basic Kit (82-6850); CereLink ICP Sensor Metal Skull (82-6851); CereLink ICP Sensor Plastic Skull (82-6852); CereLink ICP Sensor Ventricular Catheter Kit (82-6854)

Indications for Use *(Describe)*
CereLink ICP Sensor Basic Kit (82-6850); CereLink ICP Sensor Metal Skull (82-6851); CereLink ICP Sensor Plastic Skull (82-6852)
Indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only.

CereLink ICP Sensor Ventricular Catheter Kit (82-6854)
Indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage 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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510(k) Summary

I. Submitter

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Establishment Registration Number: 1226348

Contact: Megan Palumbo
Phone: (508) 828-3571
Fax: (508) 977-6979

Date of Submission: September 29, 2017

II. Device

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

III. Predicate Device

The predicate device for this submission is the Codman Microsensor Kits (K153347), which was cleared on August 19, 2016.

IV. Device Description

The CereLink ICP Sensor Kits are used to monitor intracranial pressure (ICP) through either a stand-alone probe, or a probe coupled with an External Ventricular Drainage (EVD) catheter. The probe, also known as the CereLink ICP Sensor is intended to be used in conjunction with all of Codman's neuromonitoring devices: the Codman ICP Express Monitor (product code 82-6634) and the DirectLink ICP Module (product code 82-6828). The ICP Express and DirectLink are intended for use in ICUs. The CereLink ICP Sensor converts the pressure sensor 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 Codman ICP Express or DirectLink as a result of the probe modifications described in this submission.

The CereLink ICP Sensor contains a small, thin pressure sensor used to measure the intracranial pressure. The sensing element uses a strain gauge located at the tip of the probe. The sensing element is protected by a titanium housing and is exposed to the environment via a silicone membrane. The sensor is connected

via wires to a plastic connector housing, and the wires are snaked through a nylon catheter. The connector housing includes a compensation/calibration passive circuit on a Printed Circuit Board (PCB). Additionally, the CereLink ICP Sensor's connector housing includes a new memory PCB board. When the CereLink ICP Sensor is used with either the ICP Express or DirectLink, it functions identically to the cleared predicate Codman Microsensors. Additionally, the connector housing has an electrical connector to attach to any of the monitoring devices.

The CereLink ICP Sensor Kits include components needed to facilitate the surgical implantation of the Cerelink ICP sensor. The components that will be included with the proposed CereLink ICP Sensor Kits are currently cleared devices, and are identical to the components currently packaged within the predicate Codman Microsensor Kits (i.e. there are no changes being made to the kit components, only the ICP sensor is being modified). Each component and their function are described in the Description section of the Instructions for Use for each kit.

V. Indications for Use

The table below describes the Indications for Use statements for each of the 4 proposed CereLink ICP Sensor Kit product codes.

CereLink ICP Sensor Kit Indications for Use		
Device Description	**Proposed Product Code**	**Proposed Indications for Use**
CereLink ICP Sensor Basic Kit	82-6850	Use of the CERELINK ICP SENSOR Basic Kit is indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only.
CereLink ICP Sensor Metal Skull Bolt Kit	82-6851	Use of the CERELINK ICP SENSOR Metal Skull Bolt Kit is indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications.
CereLink ICP Sensor Plastic Skull Bolt Kit	82-6852	Use of the CERELINK ICP SENSOR Plastic Skull Bolt Kit is indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only.
CereLink ICP Sensor Ventricular Catheter Kit	82-6854	Use of the CERELINK ICP SENSOR Ventricular Catheter Kit is indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.

VI. Comparison to Predicate Device

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

- the same indications for use,
- the same intended use,
- the same fundamental scientific technology,
- incorporates the same basic design (strain gauge ICP sensor connected to a plastic connector housing),
- incorporates the same materials for the implantable portion of the device,
- packaged and sterilized using the same packaging design, materials, and processes.

The minor differences between the predicate and subject device are contained within the plastic connector housing:

- a slight difference in device design (shape of plastic connector housing top lid, addition of PCB and PCB retainer inside top lid),
- pad printing replaces the paper label on the plastic connector housing (non-implantable component, only in contact with intact skin), and
- the device labeling was updated (i.e. product labels, Instructions for Use and packaging art work).

The table below details the comparison of the predicate and subject devices.

Comparison of Predicate and Proposed ICP Sensor Kits		
Characteristic	**Predicate Device:** **Codman Microsensor Kits (K153347)**	**Subject Device:** **CereLink ICP Sensor Kits (This Submission)**
FDA Product Code	GWM	Same
Classification	21 CFR 882.1620	Same
Classification Name	Device, Monitoring, Intracranial Pressure	Same
Indication for Use	**62-6631, 62-6632 & 62-6638** Indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only. **62-6633, 62-6653** Indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.	Same as predicate: **82-6850, 82-6851 & 82-6852** Indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only. **82-6854** Indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.
Contraindications (82-6850)	This kit is not designed, sold, or intended for any use except as indicated. This kit is not designed, sold, or intended for use as a therapeutic device.	Same
Contraindications (82-6851, 82-6852)	Use of the skull bolt is contraindicated in children less than one year of age.	Same

Comparison of Predicate and Proposed ICP Sensor Kits		
Characteristic	**Predicate Device: Codman Microsensor Kits (K153347)**	**Subject Device: CereLink ICP Sensor Kits (This Submission)**
	This kit is not designed, sold, or intended for any use except as indicated. This kit is not designed, sold, or intended for use as a therapeutic device.	
Contraindications (82-6854)	Ventriculostomy is contraindicated in patients with coagulopathy, or active infection in the area of the catheter. Use of the Ventricular Catheter is contraindicated in children less than one year of age. This kit is not designed, sold, or intended for any use except as indicated.	Same
Device Materials		
Printed Circuit Board (PCB) inside plastic connector housing	Materials are the same for the predicate and proposed devices.	
Memory chip PCB inside plastic connector housing	N/A	Materials are the same as those used in the predicate PCB inside the plastic connector housing.
Solder Wires	Materials are the same for the predicate and proposed devices.	
Thru-hole resistor located inside plastic connector	Materials are the same for the predicate and proposed devices.	
Epoxy Glue to cap tip of sensor and to join titanium housing to catheter tubing	Materials are the same for the predicate and proposed devices.	
Catheter 100cm tubing	Materials are the same for the predicate and proposed devices.	
Printing on the lid of the plastic connector housing	Paper label	Pad printing with ink
Sensor Top Label for the plastic connector housing. Includes Product Name, space to enter zero reference number and updated symbols.	Paper, adhesive and laminate	N/A
Sensor Bottom Label on plastic connector housing	Materials are the same for the predicate and proposed devices.	
Catheter Strain Relief	Materials are the same for the predicate and proposed devices.	
Titanium Case	Materials are the same for the predicate and proposed devices.	
Silicone Membrane	Materials are the same for the predicate and proposed devices.	
Plastic Connector Housing	Materials are the same for the predicate and proposed devices.	
Retainer (in plastic connector housing)	N/A	Materials are the same as those used in the predicate plastic connector housing.

Comparison of Predicate and Proposed ICP Sensor Kits		
Characteristic	**Predicate Device: Codman Microsensor Kits (K153347)**	**Subject Device: CereLink ICP Sensor Kits (This Submission)**
Note: There is no change to the material used in the components provided with the proposed CereLink ICP Sensor Kits as compared to the current kits.		
Packaging Materials		
Pouch (82-6850, 82-6851, 82-6852, 82-6854)	Materials are the same for the predicate and proposed packaging materials.	
Unit Box (82-6850, 82-6851, 82-6852)		
Unit Box (82-6854)		
Blister Lid (82-6850, 82-6851, 82-6852)		
Blister Lid (82-6854)		
Blister Tray (82-6850, 82-6851, 82-6852, 82-6854)		
Device Characteristics		
MRI claim	1.5T and 3T Conditional	Same
Sterilization	Ethylene Oxide	Same
Sterility Assurance Level (SAL)	10^{-6}	Same
Shelf Life	2 years	Same
Energy Modality	5 volts DC when connected to the ICP monitoring device	Same
Microsensor Dimensions	Dimensions are the same for predicate and proposed device.	
Sensing Element	Strain gauge silicon microchip	Same
Functional Pressure Range	-50mmHg to 250mmHg	Same
Functional Over Pressure Range Without Damage	-700mmHg to 1250mmHg	Same
Input/Output Impedance	1000 ohms nominal	Same
Output Signal (sensitivity)	5uV/V/mmHg	Same
Zero Drift	No greater than 5mmHg over 30 days	Same

VII. Performance Data

The following performance testing (see "Summary of Testing" table below) has been conducted in support of the substantial equivalence determination. All testing was performed on final sterile devices unless otherwise specified.

Because the proposed CereLink ICP Sensor is almost identical to the predicate Codman Microsensor, Codman leveraged many verification tests from the previously cleared Codman Microsensor (K153347). Please see the Summary of Testing table below which identifies the types of tests that were both leveraged from the predicate device, as well as performed on the subject device. All test results were deemed acceptable.

Summary of Testing			
Test	**Standards**		**Result**
Bench Testing	EN 62366:2008	Application of usability engineering to medical devices	Pass - subject device design met the established acceptance criteria and is therefore substantially equivalent to the predicate
	ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Imaging	
	ASTM F2182-11a	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	
	ASTM F2119-07	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	
	ASTM F2213-06	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	
	ASTM F2503-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	
Electrical Safety and Electromagnetic Compatibility Testing	IEC 60601-1 – Part 1	General requirements for basic safety and essential performance	Pass - subject device design met the established acceptance criteria and is therefore substantially equivalent to the predicate
	IEC 60601-1-2	Collateral Standard: Electromagnetic disturbances - Requirements and tests	
	IEC 60601-1-6	Collateral standard: Usability	
	IEC 60601-1-9	Collateral Standard: Requirements for environmentally conscious design	
Sterilization	EN ISO 11135: 2014	Validation and Routine Control of Ethylene Oxide Sterilization	Pass - subject device design met the established acceptance criteria and is therefore substantially equivalent to the predicate
	EN ISO 10993-7:2008/AC2009	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	
	EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	
	ANSI ST72:2011	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	
Shelf Life – Functionality Testing Complete after Two Year Accelerated Aging	EN ISO 11607-1: 2009 EN ISO 11607-2: 2006	Packaging for Terminally Sterilized Medical Devices: Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems – Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes	Pass - subject device design met the established acceptance criteria and is therefore substantially

			equivalent to the predicate
Biocompatibility – ICP Probe Tip and Tubing & Electrical Housing Connector	EN ISO 10993-1:2009/AC2010	Biological Evaluation of Medical Devices: Part 1: Evaluation and testing with a risk management process	Non-cytotoxic, Non-sensitizing, Non-irritating, Non-toxic, Non-pyrogenic, Non-irritant, Non-mutagenic, Non-clastogenic, Non-toxic, and Met USP 37 <661> limits where applicable Subject device design met the established acceptance criteria and is therefore substantially equivalent to the predicate

Bench Testing

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

Electrical Safety and Electromagnetic Compatibility Testing

The CereLink ICP Sensor design is compliant for Electrical Safety and EMC per IEC 60601-1 2nd and 3rd editions. The CereLink ICP Sensor is listed as an applied part within the Codman ICP Express safety reports and documentation. No additional testing was required as the updates to the new sensor do not affect the performance of the probe or ICP Express, and do not affect patient safety.

Sterilization

The sterilization method of the proposed CereLink ICP product codes is identical to the sterilization method of the predicate Microsensor Kits. The

CereLink ICP Senor Kits are sterilized via ethylene oxide and have been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135:2014, "Validation and Routine Control of a Sterilization Process for Medical Devices" and ISO 11737-2:2009, "Tests of sterility preformed in the definition, validation and maintenance of a sterilization process." Sterilization testing also demonstrated that ethylene oxide residuals can be reduced to an acceptable level in accordance with ISO 10993-7:2008, "Biological Evaluation of Medical Devices – Ethylene Oxide Sterilization Residuals" and the proposed device can be successfully adopted into Codman's existing sterilization cycle.

Shelf-Life Testing

The shelf life for the proposed CereLink ICP Sensor Kits will be 2 years (same as predicate Codman Microsensor Kits). The proposed CereLink ICP Sensor Kits device component materials and packaging materials are identical to those used for the predicate Microsensor Kits.

Biocompatibility Testing

In comparison to the predicate Microsensor Kits, the only new patient contacting material in the Cerelink ICP Sensor Kit is the pad printing ink used on the lid of the sensor's plastic connector housing. The ink will only be in contact with the patient's intact skin. Biocompatibility testing was conducted according to ISO 10993-1 and FDA's Guidance document, "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'" issued on June 16, 2016. The test results for the pad printing ink, in conjunction with the existing biocompatibility data for the predicate Microsensor Kits, demonstrates that the proposed Cerelink ICP Sensor Kits are biocompatible.

Animal Studies

No animal studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the predicate Microsensor Kits and the proposed CereLink ICP Sensor Kits.

Clinical Studies

No clinical studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the predicate Microsensor Kits and the proposed CereLink ICP Sensor Kits.

VIII. Conclusion

Based upon the same indications for use, intended use, fundamental scientific technology, comparison to the predicate device, and testing conducted, it is concluded that the CereLink ICP Sensor Kits are substantially equivalent to the predicate device, the Microsensor Kits, and therefore does not raise any new issues of safety and effectiveness.