November 20, 2018

Integra LifeSciences Corporation
Nancy MacDonald
Regulatory Affairs Manager
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K182265
Trade/Device Name: Codman Certas Plus Programmable Valve (Certas Plus Inline Small and Certas Plus Right Angle)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: August 21, 2018
Received: August 22, 2018

Dear Nancy MacDonald:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Xiaolin Zheng -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)*
K182265

Device Name
Codman Certas Plus Programmable Valve (Certas Plus Inline Small and Certas Plus Right Angle)

Indications for Use *(Describe)*
The Codman Certas Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

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

Integra LifeSciences Production Corp.
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On behalf of:
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Date of Preparation: November 1, 2018

II. Device(s)

510(k) Number	K182265
Device Proprietary Name	Codman Certas Plus Programmable Valve (Certas Plus Inline Small and Certas Plus Right Angle)
Common Name	Hydrocephalus Shunt
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)
Regulatory Classification	II
Product Code	JXG

III. Predicate Device(s)

The predicate and reference devices for this submission are:

	510(k) Number	Date Cleared	Title
Predicate	K152152	Oct. 27, 2015	Codman Certas Plus Programmable Valve
Reference	K053107	Jan. 19, 2006	Codman Hakim Programmable Valve with/without SiphonGuard

IV. Device Description(s)

This submission includes two additional configurations of the Codman Certas Plus Programmable Valve: Certas Plus Inline Small and Certas Plus Right Angle. The Codman Certas Plus Programmable Valves are sterile,

single use, implantable devices designed for shunting cerebrospinal fluid (CSF) for the treatment of hydrocephalus.

The Codman Certas Plus Programmable Valve is a pressure-regulating valve utilizing the ruby ball-in-cone principle with a pressure inducing spring design. Intraventricular pressure is maintained by the ball and cone valve seat design. As the differential pressure across the shunt increases, the ball further displaces from the cone, through which CSF flows, thereby increasing flow and re-establishing the selected pressure. The ball is manufactured of synthetic ruby, as is the matching cone. Together these components provide a precise fit for regulating the flow of CSF through the valve.

The valve is available with 8 different performance settings for constant intraventricular pressure and drainage of CSF. Seven (7) of the settings provide a change in operating pressure, with a range of 25 to 215 mmH_2O. The eighth (8) setting provides a minimum opening pressure of '400' mmH_20, thus allowing a physician to turn the valve "virtually off" without the need to surgically remove the valve to limit flow. The pressure of the valve is set preoperatively and can be noninvasively changed post-implantation by using the Codman Certas Tool Kit.

V. Indications for Use

The Indications for Use statement of the proposed device remains identical to the predicate device.

Equivalence Comparison	Indications for Use
Codman Certas Plus Programmable Valve (Predicate K152152)	The Codman Certas Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.
Codman Hakim Programmable Valve (Reference K053107)	The Codman Hakim Programmable Valves (CHPV) are implantable devices that provide constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.
Codman Certas Plus Inline Small and Certas Plus Right Angle Programmable Valves (Subject of This Submission - K182265)	The Codman Certas Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

VI. Comparison to Predicate and Reference Devices

The Codman Certas Plus Inline Small and Right Angle Programmable Valves are substantially equivalent to the predicate Codman Certas Plus Programmable Valve, which has been cleared under K152152 on October 27, 2015. The Certas Plus Inline Small and Right Angle Valves have the

same intended use, design principles, operational principles and materials as the predicate Certas Plus Programmable Valve. Compared to the predicate device, the Codman Certas Plus Inline Small and Right Angle valves include the modifications listed in Table 1.

The Certas Plus Right Angle Valve is also similar in design to the reference device, the Codman Hakim Programmable Valve, Right Angle (K053107).

Table 1. Proposed Modifications for the Codman Certas Plus Programmable Valve

Device	Modification	Rationale
Certas Plus Inline Small	• Smaller silicone housing and reservoir • Curved silicone housing • Angled proximal connector • Angled distal connector (applicable to valves without unitized catheters and valves without SiphonGuard) • Modified silicone backing to accommodate silicone housing • Needle Guard material changed to Polyethersulfone (PES). PES is currently used for other Certas Plus parts • Modification to the inner blister packaging	Minor modifications are being introduced to respond to market demand without changing the fundamental scientific technology or the intended use.
Certas Plus Right Angle	• Right angle silicone housing • Right angle proximal connector • Angled distal connector (applicable to valves without unitized catheters and valves without SiphonGuard) • Modified silicone backing to accommodate silicone housing • Needle Guard material changed to Polyethersulfone (PES). PES is currently used for other Certas Plus components.	Minor modifications are being introduced to respond to market demand without changing the fundamental scientific technology or the intended use. A right-angle configuration is currently available with the legally marketed reference device, the Codman Hakim Programmable Valve (K053107).
Labeling	Revised the labeling to include the Certas Plus Inline Small and Certas Plus Right Angle Valves. Added details to MRI Safety Section ('MRI Additional	Labeling updates to reflect the proposed valve configurations with no changes to the indications or intended use. Additional details requested from Codman EU Notified Body.

Table 1. Proposed Modifications for the Codman Certas Plus Programmable Valve		
Device	**Modification**	**Rationale**
	Information') to clarify how the valve was MR tested.	

VII. Performance Data

The following performance data is provided in support of the substantial equivalence determination.

Verification Testing

The following table summarizes the design verification activities. All samples in design verification testing met predefined acceptance criteria, and the proposed devices passed design verification test activities. These test results, in conjunction with the similarities to the predicate device, demonstrate that the Certas Plus Programmable Inline Small and Right Angle Valves are substantially equivalent to the predicate device.

Table 2: Design Verification Activities – Codman Certas Plus Inline Small and Right Angle Programmable Valves		
Test	**Test Method Summary**	**Results**
Shunt Safety and Performance Testing	Testing per ISO 7197:2009 standard for shunt safety and performance including the following clauses: • 4.2. Radiopacity • 4.3. Biocompatibility • 4.4. Resistance to leakage • 4.5. Control of the implanted shunt • 4.6. Pressure-flow characteristics • 4.7. Identification of shunts in vivo • 4.8. Ability to withstand overpressure • 4.9. Dynamic breaking strength • 4.10. Behavior under MR imaging conditions • 4.11. Bursting pressure • 5.1.1. Reflux performance • 8.2.d. Method for puncture and indication of how often puncturing is possible	PASS
Shelf Life Study	Testing per ISO 7197:2009 standard for shunt safety and performance following accelerated aging. Clauses related to mechanical performance of the valve were tested to specifically stress the valve's silicone housings.	PASS
Sterilization	Testing per ISO 17665-1: 2006 and ISO 17665-2: 2009 for sterilization of healthcare products, moist heat. • Confirm assembly process does not create a higher risk of bioburden. • Test ability of Certas Plus Inline valve sterilization cycle to sterilize the subject devices. o Natural Product Resistance Test o Microbial Challenge	PASS

Transit Testing	ISO 11067-1: 2009 and ISO11607-2: 2006: Packaging for Terminally Sterilized Medical Devices • Confirm that unit box and double blister prevents damage to the product in normal conditions of transit, handling, and storage in accordance with ISTA 3A. • Vibration, drop, and environmental conditioning o (Packaged-Products for Parcel Delivery System Shipments 70kg (150 lbs) or Less (standard, small, flat or elongated).	PASS; Cosmetic defects observed on unit box with no effect on packaging or valve performance.
Valve Fixation Testing	• Confirm that silicone strength of Certas Plus Inline Small valve suture flange is no worse than the predicate device. • Test compatibility of bone screw fixation with Certas Plus Right Angle valve per ISO 7197:2009 method of Dynamic Breaking Strength.	PASS
Valve Flexibility Testing	Measure force to flex subject devices to known curvature compared to predicate device.	PASS; Certas Plus Inline Small valve is more flexible and Certas Plus Right Angle valve is equivalent to predicate device.
Adjustment and Indication Testing	Verify ability to use Codman CERTAS toolkits to adjust and indicate a valve.	PASS

Validation Testing

Simulated Post-Implantation Use

Codman conducted validation testing with clinicians which included indication and adjustment post-implantation using simulated skin thicknesses.

Table 3: Design Validation Activities – Codman Certas Plus Inline Small and Right Angle Programmable Valves

Test	Test Method Summary	Results
System Safety Study	Clinicians evaluated the maximum acceptable rate for false positives and maximum success rate for completing a full procedure. Testing conducted on a simulated head model with variable valve orientation.	PASS

Test results demonstrated that the acceptance criteria were met; therefore, the Codman Certas Plus Programmable Inline Small and Right Angle Valves conform to the expected device performance and intended use. Results of the verification and validation testing have demonstrated that the proposed valves are substantially equivalent to the predicate Codman

Certas Plus Programmable Valve, and that the modifications do not impact the safety or effectiveness of the proposed valves.

Magnetic Resonance Imaging

The metallic components of the proposed Certas Plus Inline Small Valve and Certas Plus Right Angle Valve are the same as the current Certas Plus Programmable Valve. Since there were no changes to the metallic components within the valve assembly, there are no additional risks associated with the MRI safety of the proposed valves.

Biocompatibility Testing

The materials of the proposed Certas Plus Inline Small Valve and Certas Plus Right Angle Valve are the same as the current Certas Plus Programmable Valve and are sterilized using the same sterilization method as the predicate devices in the Certas Plus Programmable Valve product family.

Animal Studies

No animal studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the proposed devices to the predicate device, and from result of bench testing.

Clinical Studies

No clinical studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the proposed devices to the predicate device, and from result of bench testing.

Conclusion

Based upon the intended use, design, materials, function, comparison to currently marketed devices, and testing performed, it is concluded that the Codman Certas Plus Inline Small and Right Angle Valves are substantially equivalent to the predicate Codman Certas Programmable Valve (K152152) and, therefore, do not raise any new questions of safety and effectiveness.