DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 27, 2015

Medos International Sarl
Ms. Jocelyn Raposo
Project Manager, Regulatory Affairs
Chemin-Blanc 38
Le Locle, Switzerland CH-2400

Re: K152152
Trade/Device Name: Codman Certas Plus Programmable Valve
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: July 31, 2015
Received: August 3, 2015

Dear Ms. Jocelyn Raposo:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152152

Device Name

Codman Certas Plus Programmable Valve

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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CODMAN NEURO

DePuy Synthes

COMPANIES OF Johnson & Johnson

510(k) Summary

I. Submitter

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Contact Person: Jocelyn Raposo
Date of Submission: July 31, 2015

II. Device

Name of Device	Codman Certas Plus Programmable Valve
Common Name	Hydrocephalus Shunt
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)
Regulatory Class	II
Product Code	JXG

III. Predicate Device

Codman Hakim Programmable Valve, K974739.

The following reference devices were used in this submission:
Codman Certas Plus Programmable Valve, K143111
Codman Certas Programmable Valve, K112156

IV. Device Description

The Codman Certas Plus Programmable Valve is a sterile, single use, implantable device 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.

IV. Device Description (Cont.)

The valve is available with 8 different performance settings for constant intraventricular pressure and drainage of CSF. Seven (7) of the settings provide for a change in operating pressure, with a range of 25 to 215 mmH_2O. The eighth 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, which employs magnetic force to select one of the 8 settings.

V. Indications for Use

The Indications for Use statement is identical to the predicate Codman Hakim Programmable Valve.

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 Device

Codman has modified the intended use of the Codman Certas Plus Programmable Valve to include ventriculo-atrial (VA) shunting. Currently, there is a contraindication for VA shunting in the instruction for use (IFU) that has been removed, thereby allowing Certas Plus Programmable Valves without Bactiseal antimicrobial catheters to be used for VA shunting.

The Codman Certas Plus Programmable Valve with the proposed intended is substantially equivalent to the predicate Codman Hakim Programmable Valve which has been cleared for VA shunting under K974739 on July 1, 1998. The Codman Hakim Programmable Valve has the same intended use, design principles, and similar operational principles and materials as the Certas Plus Programmable Valve.

The labeling modifications are specified in **Table 1**.

Table 1. Labeling Modifications Proposed for the Codman Certas Plus Programmable Valve		
Component	**Modification**	**Rationale**
Instructions for Use (IFU)	The IFU has been updated to remove the contraindication for draining cerebrospinal fluid to the atrium (also known as ventriculo-atrial (VA) shunting); thereby allowing Certas Plus Programmable Valves without Bactiseal antimicrobial catheters to be used for VA shunting. Precautions regarding ventriculo-atrial (VA) shunting have been added to the IFU.	Removing the contraindication allows physicians the option of using the Certas Plus Programmable Valve without Bactiseal antimicrobial catheters for VA shunting. No changes are being made to the technological characteristics (i.e. design, materials, and function) of the Certas Plus Programmable Valve.

VII. Performance Data

Codman previously received clearance for the Certas Plus Programmable Valve via K143111; all performance testing included in that submission pertains to the Certas Plus Programmable Valve described in this submission as well.

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

Bench Testing

Bench testing was performed to demonstrate that the Codman Certas Plus Programmable Valve can be used for VA shunting. The testing consisted of the following:

- Reflux testing in accordance with ISO 7197:2009 *Neurosurgical Implants – Sterile, Single-Use Hydrocephalus Shunts and Components* and ASTM F647:1994 (R2006) *Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application*
- Shelf Life testing

The test results met the acceptance criteria; therefore, the Codman Certas Plus Programmable Valve conforms to the expected device performance and proposed intended use. Results of verification testing have demonstrated that the Codman Certas Plus Programmable Valve with the proposed intended use for VA shunting is substantially equivalent to the predicate Codman Hakim Programmable Valve and does not raise new questions of safety and effectiveness.

Biocompatibility Testing

The Certas Plus Programmable Valve components and materials have not changed, but the distal catheter (without Bactiseal antimicrobials), provided with the valve, can now be placed into direct contact with blood when used for VA shunting. The same distal catheter is currently cleared for use with the predicate Codman Hakim Programmable Valve (K974739) for VA shunting; the only difference is the sterilization method. As a result, Codman performed a biocompatibility evaluation in accordance with ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*, ISO 10993-4 *Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood,* and FDA draft guidance, *Use of International Standard ISO 10993 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing,* published April 23, 2013. The evaluation concluded that additional biocompatibility testing was not required.

Animal Studies

No animal studies were required as appropriate verification of the new intended use was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing and the biocompatibility evaluation.

Clinical Studies

No clinical studies were required as appropriate verification of the new intended use was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing and the biocompatibility evaluation.

VIII. Conclusion

Based upon the intended use, design, materials, function, comparison to currently marketed devices, and testing performed by Codman & Shurtleff, Inc., it is concluded that the Codman Certas Plus Programmable Valve with the proposed intended use for VA shunting is substantially equivalent to the predicate Codman Hakim Programmable Valve and therefore, does not raise any new questions of safety and effectiveness.