October 25, 2018

Integra LifeSciences Corp.
Nancy MacDonald
Regulatory Affairs Manager
11 Cabot Blvd.
Mansfield, Massachusetts 02048

Re: K181902
Trade/Device Name: Codman Certas Plus Electronic Tool Kit
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: September 25, 2018
Received: September 26, 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)*
K181902

Device Name

Codman Certas Plus Electronic Tool Kit

Indications for Use *(Describe)*

The Codman Certas Plus Electronic Tool Kit allows the non-invasive reading or adjustment of the valve setting for the Codman Certas and Certas Plus Programmable Valves.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

**I. Submitter**

Integra LifeSciences Corp.
11 Cabot Blvd
Mansfield, MA 02048

Primary Contact: Nancy MacDonald
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Secondary Contact: Jocelyn Raposo
Phone: (781) 971-5688

Date of Preparation: September 25, 2018

**II. Device**

| | |
|---|---|
| 510(k) Number | K181902 |
| Name of Device | Codman Certas Plus Electronic Tool Kit |
| 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**

The predicate device for this submission is:

| 510(k) Number | Date Cleared | Title |
|---|---|---|
| K143111 | February 19, 2015 | Codman Certas Tool Kit |

**IV. Device Description**

The Certas Plus Electronic Tool Kit is used to non-invasively read or adjust the setting of a Certas or Certas Plus Programmable Valve before and after implantation in the treatment of hydrocephalus. The Certas Plus Electronic Tool Kit consists of the following tools: Locator/Indicator Tool, Adjustment Tool and X-Ray Overlay Tool. The Locator/Indicator Tool facilitates correct placement of the Adjustment Tool over a pre-implanted valve in the packaging or a post-implanted valve, and measures the valve's magnetic field to display the valve setting. The Adjustment Tool adjusts the valve to one of the 8 valve settings. The magnets in the Adjustment Tool couple with the magnets in the rotating construct of the valve, causing the rotating construct to lift and follow the Adjustment Tool as it is rotated to one of 8 valve settings.

**V. Indications for Use**

The Indications for Use statement for the Certas Plus Electronic Tool Kit is identical to the predicate Certas Tool Kit:

The Codman Certas Plus Electronic Tool Kit allows the non-invasive reading or adjustment of the valve setting for the Codman Certas and Certas Plus Programmable Valves.

**VI. Comparison to Predicate Device**

Compared to the predicate device, the proposed Certas Plus ElectronicTool Kit includes the modifications listed in Table 1.

**Table 1: Similarities and Differences – Certas Tool Kit and Certas Plus Electronic Tool Kit**

| | **Certas Took Kit (Predicate)** | **Certas Plus Electronic Tool Kit (this submission)** |
|---|---|---|
| **510(k) Number** | K143111 | K181902 |
| **Indications for Use** | The Codman Certas Tool Kit allows the non-invasive reading or adjustment of the valve setting. | The Codman Certas Plus Electronic Tool Kit allows the non-invasive reading or adjustment of the valve setting for the Codman Certas and Certas Plus Programmable Valves. |
| **Handheld Tools** | Locator tool (low profile + adjustable height)<br>Indicator tool<br>Adjustment tool | Locator/Indicator tool<br>Adjustment tool |
| **Operating Principle** | Locator Tool: Facilitates correct placement of the Adjustment Tool and Indicator Tool over an implanted valve.<br><br>Indicator Tool: Incorporates a detection wheel (indication dial) that aligns the valve's magnetic field to display the valve setting.<br><br>Adjustment Tool: The magnets in the Adjustment Tool couple with the magnets in the rotating construct of the valve, causing the rotating construct to lift and follow the Adjustment Tool as it is rotated to one of 8 valve settings. | The Locator and Indicator Tools have been combined into one tool.<br><br>Locator/Indicator Tool facilitates correct placement of the Adjustment Tool over an implanted valve.<br><br>The Locator/Indicator Tool incorporates a detection wheel (indication dial) that measures the valve's magnetic field to display the valve setting.<br><br>Adjustment Tool: The magnets in the Adjustment Tool couple with the magnets in the rotating construct of the valve, causing the rotating construct to lift and follow the Adjustment Tool as it is rotated to one of 8 valve settings. |
| **Energy Type** | Mechanical, magnetic energy, not battery operated | Locator/Indicator: Battery operated<br>Adjustment Tool: Magnetic energy |

| Table 1: Similarities and Differences – Certas Tool Kit and Certas Plus Electronic Tool Kit | | |
|---|---|---|
| | **Certas Took Kit (Predicate)** | **Certas Plus Electronic Tool Kit (this submission)** |
| **Location/Indication Feedback** | Location: No location feedback; the user is required to manually palpate to determine the valve location<br><br>Indication: display a mechanical indication dial for the determination of valve performance setting | Location: LED screen is used to display location feedback to aid in the alignment of the Locator/Indicator Tool with the valve mechanism center<br><br>Indication: LED screen is used to display an indication dial for the determination of valve performance settings. |
| **Materials – Patient Contacting** | • Polycarbonate<br>• Polycarbonate, Aluminum with anodized surface, Decal<br>• Acetal Copolymer | • Polycarbonate and acrylonitrile butadiene styrene (PC/ABS)<br>• Pad Printing Ink (blue)<br>• Pad Printing Ink (White) |
| **Materials – Not Patient Contacting (Locator Tool)** | There are various Locator and Indicator Tool materials including, but not limited to:<br><br>• Polycarbonate<br>• Acetal (Delrin) | Locator/Indicator Tool:<br>• PC/ABS<br>• MuMetal ASTM-A753 Alloy 4<br>• Brass<br>• Polycarbonate<br>• ROHS Compliant Electronics<br>• Nickel plated Stainless Contact and Copper Wire<br>• Polyimide<br>• Insulated Copper Wire<br>• CR 123A, Lithium Battery<br>• Thermal Transfer Polyester<br>• Polyester Film |
| **Materials – Not Patient Contacting (Adjustment Tool)** | There are various Adjustment Tool materials including, but not limited to:<br>• Polycarbonate<br>• Acetal (Delrin) | Adjustment Tool:<br>• PC/ABS TPE<br>• PC/ABS<br>• Neodymium Magnets<br>• Stainless Steel<br>• Thermal Transfer Polyester |
| **Protective Carrying Case** | Yes | Yes |
| **Accessory tool** | X-ray overlay | X-ray overlay |
| **Sterilization** | NA, non-sterile | NA, non-sterile |

**VII. Performance Data**

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

## Verification Testing

The following table summarizes the design verification activities. All samples in design verification testing met predefined acceptance criteria, and the proposed device passed design verification test activities. These test results, in conjunction with the similarities to the predicate device, demonstrate that the Certas Plus Electronic Tool Kit is substantially equivalent to the predicate device.

| Table 2: Design Verification Activities Codman Certas Plus Electronic Tool Kit | | |
|---|---|---|
| **Test** | **Test Method Summary** | **Results** |
| Comprehensive Design Verification Study | Testing verified that design outputs adequately met the specified designed inputs including but not limited to the following:<br>• Product requirements verified against drawing specifications for predicate<br>• Performed to verify expected performance of indication and adjustment features<br>• Verify tool screen sequence and iconography features<br>• Verify mechanical performance of assembly and carrying case<br>• Ensure that a successful indication is provided across the range of tissue thickness<br>• Verify that electronic components are incorporated such that their rated maximums are not exceeded during normal use. This includes component thermal rating, operating temperature, electrical voltage withstanding, electrical current capacity and other parameters applicable to specific components | PASS |
| Electrical Safety and Ingress Testing | Protect against ingress with a IP4X rating. Per IEC 60601-1 (Edition 3.1) | PASS |
| Force Tests | Device capable performing intended function after minimum 2700 cycles | PASS |
| User Feedback Verification | • Verify user interaction requirements associated with screen and user feature design and function.<br>• Measure the time to receive an indication from the device.<br>• Confirm that users receive appropriate feedback device during adjustment<br>• Verify system failure messages. | PASS |
| Environmental | Environmental chamber testing durability across typical operational conditions. Demonstrate that environmental storage conditions experienced by the tool kit will not affect its functionality. | PASS |
| Transit Testing | • Confirm that device and case are secure during transit and that case shall prevent damage to the product in normal conditions of transit, handling, and storage in accordance with ISTA 3A.<br>• Vibration, drop, and environmental conditioning<br>  ○ (Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or Less (standard, small, flat or elongated). | PASS |
| Disinfection Compatibility | • Demonstrate efficacy of the reprocessing procedure used to disinfect reusable components of the device to achieve low level disinfection using 70% Isopropyl Alcohol Surface Wipes.<br>• Confirm no appreciable signs of deterioration of the enclosure after 1000 disinfection cycles. | PASS |

## Validation Testing

### Biocompatibility Testing

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* and FDA guidance, *Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process',* published June 16, 2016.

The Certas Plus Electronic Tool Kit is considered a surface device with limited skin contact (≤ 24 hours). Biocompatibility testing performed on the subject device, the Certas Plus Electronic Tool Kit, with successful results, confirming that no new issues of safety with successful results, confirming that no new issues of safety and effectiveness are raised. The following tests in Table 3 were conducted on the patient contacting components: cytotoxicity, sensitization and irritation. The device met all predefined acceptance criteria and passed biocompatibility testing.

**Table 3: Biocompatibility Testing for the Locator/Indicator Bottom Housing of the Proposed Device**

| Biocompatibility Test | Summary of Results | Conclusion |
|---|---|---|
| Cytotoxicity | No cytotoxicity or cell lysis was noted in any of the test wells. No pH shift was observed at 48 hours. | Non-cytotoxic |
| Sensitization | The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig test. | Not considered a sensitizer |
| Irritation | There was no erythema and no edema observed on the skin of the animals treated with the test article extract. The Primary Irritation Index for the test article extracts of sodium chloride and sesame oil were both calculated to be 0.0. The irritation responses to the test article extracts of sodium chloride and sesame was categorized as negligible. | Non-Irritant |

All tests results are acceptable and conform to the acceptance criteria outlined in the applicable ISO 10993 standards. The test results demonstrate that the materials in the proposed device are non-cytotoxic, non-sensitizing, and non-irritating and thus biocompatible per ISO 10993-1. Therefore, the proposed Certas Plus Electronic Tool Kit is substantially equivalent to the predicate device with respect to biocompatibility.

**Simulated Post-Implantation Use**

Codman conducted validation testing with clinicians which included a system safety study and qualitative assessment of clinical acceptability. All acceptance criteria were met.

| Table 4: Design Validation – Certas Plus Electronic Tool Kit | | |
|---|---|---|
| **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 clinically relevant implant locations to create angular variability. | PASS |
| Qualitative Assessment of Clinical Acceptability | After completing simulated use testing with the Certas Plus Electronic Tool Kit, clinicians were asked to:<br>• Provide a qualitative assessment of:<br>  ○ Patient comfort (anticipated)<br>  ○ Clarity of information on screen<br>  ○ acceptability for use in retro-auricular placement<br>  ○ Ease of use<br>  ○ Clinical acceptability<br>• Identify images of low battery, critical low battery and graphics system failure screen and asked to identify the intent. | PASS |

Design Validation testing of the Certas Plus Electronic Tool Kit confirmed that the design outputs meet the customer requirements and confirm various user needs for the individual tools. These results demonstrate the safe and effective use of the Certas Plus Valve and the Certas Plus Electronic Tool Kit as a system for post-implant adjustment of the valve.

**Animal Studies**

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

**Clinical Studies**

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

The Certas Plus Electronic Tool Kit passed the verification and validation testing, demonstrating that it performs similarly to the predicate device, the Certas Tool Kit, with respect to design verification and validation testing.

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**VIII. Conclusion**

Based upon the intended use, design, materials, function, comparison to the predicate device, and testing performed by Codman, it is concluded that the Certas Plus Electronic Tool Kit is substantially equivalent to the predicate device.

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