February 1, 2023

Integra LifeSciences Production Corporation
Amanda Erwin
Manager, Regulatory Affairs
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K223330
Trade/Device Name: Certas Plus Programmable Valves
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: October 31, 2022
Received: November 3, 2022

Dear Amanda Erwin:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2023.02.01 11:59:50 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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and Neurodiagnostic Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223330

Device Name
Certas Plus Programmable Valves

Indications for Use *(Describe)*
The 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

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a) (1) Submitter Information	
Name and Address	Integra LifeSciences Production Corporation 11 Cabot Boulevard Mansfield, MA 02048 On behalf of: Integra LifeSciences Switzerland SARL Floor 2, Rue Girardet 29 Le Locle, Neuchatel CH-2400 Switzerland
Telephone number	(609) 627-9053
Primary Contact	Amanda Erwin
Date Summary Prepared	February 1, 2023
807.92(a) (2) Name of Device	
Trade or Proprietary Name	Certas Plus Programmable Valves
Common Name	Central Nervous System Fluid Shunt and Components
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)
Device Class	II
Product Code	JXG
807.92(a) (3) Predicate Information	
Predicate Device	Certas Plus Programmable Valves: K152152 and K182265 Certas Plus Programmable Valves: K143111 (reference device)
807.92(a) (4) Device Description	

The Certas Plus Programmable Valves are implantable, sterile, single use devices that provide constant intraventricular pressure and drainage of cerebrospinal fluid (CSF) for the management of hydrocephalus. Hydrocephalus is a condition caused by excessive accumulation of CSF in the ventricles of the brain due to a disturbance of CSF secretion, flow, or absorption, which causes a rise in intracranial pressure (ICP). To relieve ICP, CSF can be diverted through a shunting device, such as a Certas Plus Programmable Valve, to another body cavity where it is subsequently absorbed. The Certas Plus Programmable Valves can be set to eight different performance settings for intraventricular pressure and drainage of CSF. The performance settings of the valves can be set preoperatively and can also be noninvasively changed post-implantation by using the Certas Tool Kits. The Certas Tool Kits employ magnetic force to select one of eight settings.

807.92(a) (5) Indications for Use

The Certas Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

807.92(a) (6) Technological Characteristics Compared to Predicate

The proposed Certas Plus Programmable Valves have the same intended use, sterility, design principles and fundamental operation as the predicate valves. The proposed minor change in technological characteristics for the valves consists of a material change and minor dimensional and tolerance changes for various components. The changes do not raise any new questions of safety and/or effectiveness.

Component Affected	Proposed Modification	Rationale
Various Internal Components	• Replacement of Polyethersulfone (PES) with Polysulfone (PSU) in Certas Plus Programmable Valves for various internal components.	• Polyethersulfone will no longer be available for Integra to manufacture the impacted internal components with.
	• Replacement of Nylon with	• Nylon will no longer be used to

	Polysulfone (PSU) in Certas Plus programmable Valve Needle Guard internal component. • Minor dimensional and tolerance changes to internal components. A design feature in the Small and Right Angle Needle Guards will also be removed.	manufacture the impacted Certas Plus Programmable Valve Inline Valve Needle Guard internal component with. • The minor dimensional and tolerance changes to the internal components have been made to accommodate the material changes. The removal of the design feature in the Small and Right Angle Needle Guards was done to remove a design feature that was never utilized.
Labeling	• Updates made to reflect the proposed material changes, as well as administrative updates and corrections. • Inclusion of a Patient Implant Card and a Patient Information Leaflet	• Update labelling with new material and administrative updates and corrected information. • A Patient Implant Card and Patient Information Leaflet is included as the devices are MR conditional implants.

807.92(b) 1-2: Summary of Nonclinical and Clinical Testing Performed

The following performance testing has been conducted in support of the substantial equivalence determination. The testing utilized well-established methods, including those from FDA consensus standards. All testing was performed on production equivalent devices.

Performance Bench Test Results	
Test	**Conclusion**
Accelerated Aging for Shelf Life Testing per ASTM F1980	Pass
Functional Testing per ISO 7197	Pass
Functional Testing per ASTM F647	Pass
MRI Testing per ISO/TS 10974	Pass
X-Ray Testing per ASTM F640	Pass

Biocompatibility Testing Results	
Test	**Conclusion**
MTS Cytotoxicity per ISO 10993-5	Pass
Guinea Pig Maximization Sensitization Study per ISO 10993-10	Pass
Intracutaneous Irritation Study in Rabbits per ISO 10993-10	Pass
Acute Systemic Toxicity Study in mice per ISO 10993-11	Pass
Rabbit Pyrogen Study per United States Pharmacopeia 42 – NF 37	Pass
Subcutaneous Implantation Studies in Rabbits, 1 and 4 weeks per ISO 10993-6	Pass
Systemic Toxicity and Local Effects Study in Rabbits following Subcutaneous Implantation 13 weeks per ISO 10993-6 and ISO 10993-11	Pass
Bacterial Reverse Mutation Study per ISO 10993-3 and ISO/TR 10993-33	Pass
In Vitro Mouse Lymphoma Study per ISO 10993-3 and ISO/TR 10993-33	Pass
Hemolysis on Extract Study per ISO 10993-4 and ASTM F756	Pass

There are no changes in sterility as a result of the proposed material changes and minor dimensional and tolerance changes; a sterilization equivalency assessment was performed comparing the proposed device to the predicate device and deemed acceptable.

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 testing.

807.92(b) (3) Conclusion
Based upon the intended use, design, comparison to the predicate device, and testing performed, Integra LifeSciences believes that the proposed modifications to the Certas Plus Programmable Valves do not raise any new questions of safety and effectiveness, and is therefore, substantially equivalent to the predicate Certas Plus Programmable Valves.