October 14, 2022

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

Re: K221840
Trade/Device Name: Hakim Programmable Valves, Hakim Precision Fixed Pressure Valves
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: Class II
Product Code: JXG
Dated: July 18, 2022
Received: July 18, 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, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K221840

Device Name
Hakim Precision Fixed Pressure Valves
Hakim Programmable Valves

Indications for Use *(Describe)*
The Codman Hakim Precision Fixed Pressure Valve Systems are implantable devices that provide constant intraventricular pressure and drainage of cerebral spinal fluid (CSF) for the management of hydrocephalus.

The Codman Hakim Programmable Valves Systems are implantable devices that provide constant intraventricular pressure and drainage of cerebral spinal fluid (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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Integra LifeSciences-Traditional 510(k)
Hakim® Precision Fixed Pressure Valves and Hakim® Programmable Valves

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	Integra LifeSciences Production Corporation
Address	11 Cabot Boulevard Mansfield, MA 02048
Telephone number	(609) 627-9053
Primary Contact	Amanda Erwin
Date Summary Prepared	June 23, 2022
807.92(a) (2) Name of Device	
Trade or Proprietary Name	Hakim Precision Valves Hakim 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	Hakim Precision Valves and Hakim Programmable Valves: K172022 The following reference device is used in this submission: Codman Certas Plus Programmable Valve: K143111, K182265
807.92(a) (4) Device Description	
The Codman Hakim® Precision Fixed Pressure and 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 Hakim Precision Valve or Hakim Programmable Valve, to another body cavity where it is a subsequently absorbed. Both the Codman Hakim Precision Fixed Pressure and Programmable Valves are pressure regulating valves which maintain intraventricular pressure at a constant level. The Hakim Precision valves are fixed pressure valves and are available in 5 different opening pressure ranges. The Codman Hakim Programmable Valves, not having fixed pressures, permit non-invasive adjustment of the valve opening pressure. The Codman Hakim Programmable Valves can be adjusted to 18 different opening pressure settings.

807.92(a) (5) Indications for Use

The Codman Hakim Precision Fixed Pressure Valve Systems are implantable devices that provide constant intraventricular pressure and drainage of cerebral spinal fluid (CSF) for the management of hydrocephalus.

The Codman Hakim Programmable Valve Systems are implantable devices that provide constant intraventricular pressure and drainage of cerebral spinal fluid (CSF) for the management of hydrocephalus.

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

The proposed Hakim Precision Valves and Hakim 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 Hakim Precision Fixed Pressure Valves and Hakim Programmable Valves	Polyethersulfone will no longer be available for Integra to manufacture the impacted internal components with. Nylon will no longer be available to manufacture the impacted Hakim Programmable

	for various internal components. Minor dimensional and tolerance changes to internal components will also be made to the internal components to accommodate the material change. • Replacement of Nylon with Polysulfone (PSU) in Hakim programmable Valve internal component. Minor dimensional changes will be made to accommodate the material change.	Valves Needle Guard internal component with. The minor dimensional and tolerance changes to the internal components have been made to accommodate the material change or standardize component design across Integra's hydrocephalus valve portfolio.
Labeling	• Updates made to reflect the proposed material change, as well as administrative updates and corrections. • Inclusion of Patient Implant Cards and Patient Information Leaflet • The labelling for Hakim Programmable Valves has also been updated to comply with Regulation (EU) 2017/745.	• Update labelling with current information. • Patient Implant Cards and Patient Information Leaflets are included as the devices are MR conditional implants. • To comply with Regulation (EU) 2017/745.
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**
Product Shelf Life Testing per ASTM F1980	Pass
Functional Testing per ISO 7197	Pass
Functional Testing per ASTM F647	Pass
MRI Spatial Gradient Testing per ASTM F2052	Pass
X-Ray Testing per ASTM F640	Pass

Biocompatibility Testing Results	
Test	**Conclusion**
MTT and MTS Cytotoxicity Studies per ISO 10993-5	Pass
Guinea Pig Maximization Sensitization Studies per ISO 10993-10	Pass
Intracutaneous Irritation Studies in Rabbits per ISO 10993-10	Pass
Acute Systemic Toxicity Study in Mice per ISO 10993-11	Pass
Rabbit Pyrogen Studies per United States Pharmacopeia (USP 42 – NF 37)	Pass
Subcutaneous Implantation Studies in Rabbits, 1 Week 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 Studies per ISO 10993-3 and ISO/TR 10993-33	Pass
In Vitro Mouse Lymphoma Studies per ISO 10993-3 and ISO/TR 10993-33	Pass
Hemolysis on Extract Studies per ISO 10993-4 and ASTM F756	Pass

There are no changes in sterility method as a result of the proposed material change 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 Hakim Precision Valves and Hakim Programmable Valves do not raise any new questions of safety and effectiveness, and is therefore, substantially equivalent to the predicate Hakim Precision Valves and Hakim Programmable Valves.