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

March 4, 2016

Integra LifeSciences Corporation
Ms. Jennifer Siegel
Regulatory Affairs Specialist
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K152897
Trade/Device Name: Integra DP Valve Systems (including Burr Hole Reservoirs and Stainless Steel Connectors), Gravity Compensating Accessory
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: February 2, 2016
Received: February 3, 2016

Dear Ms. Siegel:

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)*
K152897

Device Name
Integra DP Valve Systems (including Burr Hole Reservoirs and Stainless Steel Connectors), Gravity Compensating Accessory

Indications for Use *(Describe)*

Integra DP Valve Systems
Integra DP Valve Systems are implantable devices which serve as a parallel flow pathway to divert cerebrospinal fluid (CSF) from the cerebral ventricles to an appropriate drainage site. They provide controlled intraventricular pressure and CSF drainage in patients with hydrocephalus or other conditions in which CSF flow and/or absorption is impaired. The very low pressure valve (blue band) is used for postoperative drainage of hygromas and other extraventricular conditions.

Burr Hole Reservoirs
Hydrocephalus valve components are elements used in the implantation of hydrocephalus valve systems. In addition, the burr hole reservoir may be used in conjunction with a ventricular catheter to access ventricular CSF.

Gravity Compensating Accessory
The Gravity Compensating Accessory is an implantable device which is implanted in series with a hydrocephalus valve to control cerebrospinal fluid (CSF) drainage from the cerebral ventricles to an appropriate drainage site. It is designed to minimize the excessive reduction in intraventricular pressure (relative to atmosphere) and CSF volume caused by the "pull" exerted by the fluid column within the outflow catheter when the patient is sitting or standing.

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.

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 Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	1-609-275-0500
Fax Number	1-609-275-5363
Establishment Registration Number	3003418325
Name of Contact Person	Jennifer Siegel
Date Prepared	September 30, 2015
807.92(a)(2) – Name of device	
Trade or Propriety Name	Integra DP™ Valve Systems (including Burr Hole Reservoirs and Stainless Steel Connectors) Gravity Compensating Accessory
Common or Usual Name	Hydrocephalus Shunts Antisiphon Device
Classification Name	Shunt, Central Nervous System And Components
Classification Panel	Neurology
Regulation	Class II, under 21 CFR 882.5550
Product Code(s)	JXG
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
Integra DP™ Valve Systems (including Burr Hole Reservoirs and Stainless Steel Connectors); K861377 Omnishunt System for Ventricular Shunting: K903844 Polypropylene Burr Hole Reservoir; K925810 Gravity Compensating Accessory; K932429	

807.92(a)(4) - Device description

The Integra DP™ Valve Systems are implantable central nervous system fluid shunt devices which incorporate two ball-in-cone valve mechanisms. They provide constant differential pressure across the valve and continuous, controlled drainage of cerebrospinal fluid (CSF) from the cerebral ventricles to the peritoneal cavity (or another appropriate drainage site). Each unidirectional valve unit consists of two ball-in-cone valve mechanisms, each enclosed in a stainless steel housing. In each ball-in-cone valve mechanism, a synthetic ruby ball is held against a cone-shaped, stainless steel seat by a stainless steel spring.

The tension of the spring determines the operating pressure of the valve. Depending on the CSF flow rate and/or the viscosity, the ball moves back and forth within the cone under the control of the spring. As the ball moves, the effective cross section of the valve through which CSF flows increases or decreases. Thus, the size of the valve opening is adjusted automatically, and the differential pressure is controlled.

A variety of system configurations are available (Standard Valve Systems, Pediatric Valve Systems, Burr Hole Shunt Systems, Valve Unit only). Most valve systems include the necessary components required for an implantation procedure (such as peritoneal and ventricular catheters, plastic subcutaneous tube passers, introducing rod, and connectors). Several color-coded pressure ranges are offered.

The Burr Hole Reservoir is a component of a central nervous system fluid shunt. It is used to connect the ventricular catheter to a silicone elastomer burr hole reservoir cap with integral side-arm leading to the valve tubing. In this configuration, it serves to transmit CSF from this catheter to the valve. It may also be used as a CSF reservoir with a ventricular catheter alone when a burr hole cap without side-arm is used. This reservoir facilitates CSF sampling or intracranial pressure measurement when the burr hole reservoir cap is punctured with a small gauge needle. Configurations include 6.4 mm or 10 mm outer diameter reservoir and regular (2.5 mm) or shallow (0.8 mm) depth. The Burr Hole reservoirs are included as a part of the Integra DP™ Burr Hole Shunt System, or the Burr Hole reservoir and cap can be ordered separately.

The Gravity Compensating Accessory (GCA) is designed to counterbalance gravity's effects on the fluid column within the outflow (drainage) catheter of an implanted shunt system. The GCA can be placed anywhere deemed appropriate by the surgeon along the distal shunt tubing. Its operating characteristics are not dependent on its location along the tubing.

The GCA consists of a silicone elastomer encased stainless steel housing with a ruby ball held in a stainless steel seat (in the vertical orientation) by two to four stainless steel balls. Each ball contributes resistance to flow within the system. Depending on the number of balls, resistance to flow is added to the resistance of the implanted valve system when the patient assumes a vertical posture. In the horizontal orientation, a minimal resistance to flow is added to the system.

807.92(a)(5) – Intended use of the device	
Indications for Use	**Integra DP™ Valve Systems** Integra DP Valve Systems are implantable devices which serve as a parallel flow pathway to divert cerebrospinal fluid (CSF) from the cerebral ventricles to an appropriate drainage site. They provide controlled intraventricular pressure and CSF drainage in patients with hydrocephalus or other conditions in which CSF flow and/or absorption is impaired. The very low pressure valve (blue band) is used for postoperative drainage of hygromas and other extraventricular conditions. **Burr Hole Reservoirs** Hydrocephalus valve components are elements used in the implantation of hydrocephalus valve systems. In addition, the burr hole reservoir may be used in conjunction with a ventricular catheter to access ventricular CSF. **Gravity Compensating Accessory** The Gravity Compensating Accessory is an implantable device which is implanted in series with a hydrocephalus valve to control cerebrospinal fluid (CSF) drainage from the cerebral ventricles to an appropriate drainage site. It is designed to minimize the excessive reduction in intraventricular pressure (relative to atmosphere) and CSF volume caused by the "pull" exerted by the fluid column within the outflow catheter when the patient is sitting or standing.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The proposed Integra DP™ Valve Systems and Gravity Compensating Accessory have the same technological characteristics compared to the predicate devices of the same name. The addition of MRI safety information to the labeling does not alter the intended use, materials of composition, manufacturing and sterilization process, or the fundamental scientific technology of the devices.

The proposed Integra DP™ Valve Systems indications for use include the claim that they "provide controlled intraventricular pressure", which was not included with the predicate cleared under K861377. This claim was cleared through the Omnishunt System, K903844, on December 28, 1990. The Omnishunt Valve and DP Valve use the same ball-in-cone valve mechanism. The only difference is that the DP Valve contains two mechanisms while the Omnishunt Valve has one.

The Burr Hole Reservoirs are available in either stainless steel or polypropylene. The polypropylene models were cleared under K925810. These devices have the same intended use. The reservoirs differ in material composition. The stainless steel burr hole reservoirs underwent non-clinical testing, as described below, to include MRI safety information in the labeling that accounts for this material difference.

807.92(b)(1-2) – Nonclinical and clinical tests submitted

Non-clinical testing was performed to support MRI Labeling for Integra Shunts and Implanted Accessories, ensuring the safety and effectiveness was maintained following device modifications. Testing included:

- Magnetically Induced Displacement Force (ASTM F2052-06e1): This test assessed if the amount of magnetically induced force on the device is less than or equal to the force on the device due to gravity. The magnetically induced force for the Integra DP™ Valve Systems, Burr Hole Reservoirs, Gravity Compensating Accessory, and connectors were considered to meet the acceptance criteria in both 1.5T and 3.0T MR environment, thus supporting the MR Conditional claim. The maximum acceptable spatial gradient was determined on the basis of the component with the largest deflection, and is listed in our labeling.

- Magnetically Induced Torque Test (ASTM F2213-06): This test assessed if the amount of magnetically induced torque on the device is less than or equal to the gravitational torque. The magnetically induced torque for the Integra DP™ Valve Systems, Burr Hole Reservoirs, Gravity Compensating Accessory, and connectors were considered to meet the acceptance criteria in both 1.5T and 3.0T MR environments, thus supporting the MR Conditional claim.

- RF Heating Test: ASTM F2182-09: The acceptance criterion for this test was that no portion of the implanted device exhibits an increase in temperature of more than 2^{o}C at a whole body averaged specific absorption rate (SAR) of 2W/kg and head average SAR of 3.2 W/kg (Normal Operating Mode). All tested implants met this acceptance criterion, thus supporting the MR Conditional Claim. Our labeling includes a statement on RF heating that the expected temperature rise is less than 0.4°C after 15 minutes of continuous scanning (in both 1.5 T and 3.0 T MR environments).

- Image Artifact Test: ASTM F2119-07: Image Artifact information was collected for the devices in both 1.5T and 3.0T MR environments. For each device, scans were made in three planes (sagittal, coronal, and axial) for T1 weighted Spin Echo. Our labeling lists the worst-case image artifact for T1 weighted Spin Echo.

- Functionality Verification Test: The valve components were tested both before and after exposure to an MR scan per our internal procedures to verify impact on pressure-flow characteristics. Results demonstrated that MR exposure had no impact on the functionality of the valves, thus supporting the MR Conditional claim.

The results of this testing have demonstrated that the Integra DP™ Valve Systems, Burr Hole Reservoirs, Gravity Compensating Accessory and connectors are MR Conditional and support the conditions as defined within the labeling.

807.92(b)(3) – Conclusions drawn from non-clinical and clinical data
The proposed Integra DP™ Valve Systems, including the Burr Hole Reservoirs and stainless steel connectors, are substantially equivalent to the currently marketed Integra DP™ Valve Systems which were previously cleared to market by the United States Food and Drug Administration (FDA) on June 19, 1986 under K861377 (Standard/Pediatric Cordis Hydrocephalus Valve Systems). In addition, the polypropylene version of the burr hole reservoirs was cleared on March 2, 1994 under K925810. The proposed Gravity Compensating Accessory is substantially equivalent to the currently marketed Gravity Compensating Accessory which was previously cleared to market by the FDA on July 20, 1994 under K932429 (Cordis Gravity Compensating Accessory). The addition of MRI safety information to the labeling does not alter the indications for use, intended use, materials of composition, manufacturing and sterilization process, or the fundamental scientific technology of the devices. The safe-use conditions provided in the proposed labeling do not impact the safety and efficacy of the proposed devices, and in fact, are being added to the labeling in order to improve the safe and effective use of the devices. The non-clinical testing has demonstrated the implanted Integra DP™ Valve Systems, including the Gravity Compensating Accessory, Stainless Steel Burr Hole Reservoirs, and associated connectors, are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the conditions defined within the labeling.