DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 24, 2016

Integra LifeSciences Corporation
Mr. Timothy Connors
Senior Regulatory Affairs Specialist
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K153041
Trade/Device Name: Integra Neurological Shunts and Accessories Products (LPV II Valves and Kits, Novus Valves and Kits, Multi-Purpose Valve, Mishler Dual Chamber Valve with Integral Connectors, Pudenz Flushing Valve with Integral Connectors, Ultra VS In-Line Valve System, Pudenz Cardiac and Infant Catheter, Pudenz Ventricular Catheter, Pudenz Peritoneal Catheter, Peritoneal Reflux Control Catheter and Peritoneal Open-Ended Catheter With Slits, Portnoy Ventricular Catheter, Neuroview Endoscopic Ventricular Catheter, Integra CSF Reservoir with Integral Connectors, Essential Shunt Kit Burr Hole Design, Essential Shunt Kit Flat Bottom Design, Connectors for Neurosurgical Use, On-Off Flushing Reservoirs, Braden Flushing Reservoir, Foltz Flushing Reservoir, Anti-Siphon Device)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: December 14, 2015
Received: December 15, 2015

Dear Mr. Connors:

This letter corrects our substantially equivalent letter of March 14, 2016.

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153041

Device Name
Integra Neurological Shunts and Accessories Products

Indications for Use *(Describe)*

LPV II Valves and Kits
The Standard-LPV II and Mini-LPV II Valves, utilized in the treatment of hydrocephalic patients, are components in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. The Mini-LPV II Valve can be used in (but is not restricted to) situations where skin erosion may be a problem, as with older patients.

Novus Valves and Kits
The Novus and Novus Mini Valves, utilized in the treatment of hydrocephalic patients, are components in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. The Novus Mini Valve can be used in (but is not restricted to) situations where skin erosion may be a problem, as with older patients. Valves with a Physiological Flow Device are intended to reduce the hazard of negative intraventricular pressure (with respect to atmospheric pressure) when the patient is sitting, standing or semi-recumbent.

Multi-Purpose Valve
The Multi-Purpose Valve, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum. Valves with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing.

Mishler Dual Chamber Valve with Integral Connectors
The Mishler Dual Chamber Flushing Valve, Flat Bottom Design, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum. Valves with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing.

Pudenz Flushing Valve with Integral Connectors
The Pudenz Flushing Valve, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. Valves with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing.

Ultra VS In-Line Valve System
The Ultra VS In-Line Valves, utilized in the treatment of hydrocephalic patients, are components in systems designed to shunt cerebrospinal fluid (CSF) from the lateral ventricles into either the peritoneal cavity or the right atrium of the heart. The in-line and burr-hole systems are designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneal cavity. A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated. The Small and Neonate Models can be used in (but are not restricted to) situations where skin erosion may be a problem, as with premature infants, pediatric patients and older patients.

Pudenz Cardiac and Infant Catheter
The Pudenz Cardiac Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into the right atrium of the heart. The Infant Cardiac

Catheter is utilized when the common facial and/or internal jugular veins are too small to accommodate the larger cardiac catheter.

Pudenz Ventricular Catheter
The Pudenz Ventricular Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum.

Pudenz Peritoneal Catheter
The Pudenz Peritoneal Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneum. A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated.

Peritoneal Reflux Control Catheter and Peritoneal Open-Ended Catheter With Slits
The Peritoneal Reflux Control Catheter and Peritoneal Open-Ended Catheter with Slits, utilized in the treatment of hydrocephalic patients, are components for systems designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneum. A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated.

Portnoy Ventricular Catheter
The Portnoy Ventricular Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum.

Neuroview Endoscopic Ventricular Catheter
The Neuroview Ventricular Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum.

Integra CSF Reservoir with Integral Connectors
The Integra CSF Reservoir provides access to the lateral cerebral ventricles via hypodermic puncture for sampling and/or injection of fluids. It is useful in obtaining CSF samples for cytological and chemical studies, for monitoring ventricular fluid pressure and for ventricular drainage. The Convertible Integra CSF Reservoir may be utilized in hydrocephalic patients as a component in systems designed to shunt CSF from the lateral ventricles into either the right atrium of the heart or the peritoneum.

Essential Shunt Kit Burr Hole Design
The CSF Control Valve, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum.

Essential Shunt Kit Flat Bottom Design
The Essential Shunt Kit – Flat Bottom Design, utilized in the treatment of hydrocephalic patients, is designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into the peritoneum. The Essential Shunt Kit – Flat Bottom Design, can be used in (but is not restricted to) situations where skin erosion may be a problem, as with older patients.

Connectors for Neurosurgical Use
Integra connectors are utilized principally in the treatment of hydrocephalic patients, as components in systems designed to shunt cerebrospinal fluid from the lateral cerebral ventricles of the brain into either the right atrium of the heart or the peritoneum.

On-Off Flushing Reservoirs
The On-Off Flushing Reservoir, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum. Reservoirs with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing.

Braden Flushing Reservoir
The Braden Flushing Reservoir, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum.

Foltz Flushing Reservoir
The Foltz Flushing Reservoir, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum.

Anti-Siphon Device
The Anti-Siphon Device, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. The device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when the patient is in a sitting, standing or erect position.

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

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, New Jersey 08536
Phone Number	(609) 936-531
Establishment Registration Number	9004007
Name of Contact Person	Timothy Connors
Date Prepared	October 16, 2015
807.92(a)(2) – Name of device	
Trade or Propriety Names	Integra Neurological Shunts and Accessories Products (LPV II Valves and Kits, Novus Valves and Kits, Multi-Purpose Valve, Mishler Dual Chamber Valve with Integral Connectors, Pudenz Flushing Valve with Integral Connectors, Ultra VS In-Line Valve System, Pudenz Cardiac and Infant Catheter, Pudenz Ventricular Catheter, Pudenz Peritoneal Catheter, Peritoneal Reflux Control Catheter, Peritoneal Open-Ended Catheter With Slits, Portnoy Ventricular Catheter, Neuroview Endoscopic Ventricular Catheter, Integra CSF Reservoir with Integral Connectors, Essential Shunt Kit Burr Hole Design, Essential Shunt Kit Flat Bottom Design, Connectors for Neurosurgical Use, On-Off Flushing Reservoirs, Braden Flushing Reservoir, Foltz Flushing Reservoir, Anti-Siphon Device)
Common or Usual Name	Hydrocephalus Shunt Systems and Components
Classification Name	Central Nervous System Fluid Shunt 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	
Equivalence is claimed to current Integra Neurological Shunts and Accessories Products, as identified below: LPV II Valves and Kits - K974708	

Novus Valves and Kits - K961859
Multi-Purpose Valve - Pre-amendment device
Mishler Dual Chamber Valve with Integral Connectors - K760784
Pudenz Flushing Valve with Integral Connectors - K760501, K760502
Ultra VS In-Line Valve System – K894072
Pudenz Cardiac and Infant Catheter - Pre-amendment device
Pudenz Ventricular Catheter - Pre-amendment device
Pudenz Peritoneal Catheter - Pre-amendment device
Peritoneal Reflux Control Catheter – K894072
Peritoneal Open-Ended Catheter With Slits – K894072
Portnoy Ventricular Catheter – Pre-amendment device
Neuroview Endoscopic Ventricular Catheter – K971617
Integra CSF Reservoir with Integral Connectors - Pre-amendment device
Essential Shunt Kit Burr Hole Design - K973525
Essential Shunt Kit Flat Bottom Design – K973525
Connectors for Neurosurgical Use - Pre-amendment device
On-Off Flushing Reservoirs - Pre-amendment device
Braden Flushing Reservoir - Pre-amendment device
Foltz Flushing Reservoir - Pre-amendment device
Anti-Siphon Device – K760785

807.92(a)(4) - Device description

Integra Neurological Shunts and Accessories are used in the treatment of hydrocephalus. Hydrocephalus is commonly treated by creating a CSF flow pathway from a cerebral ventricle to the peritoneal spaces in the abdomen or to the right atrium of the heart. This is commonly referred to as "shunting". Integra markets a full line of products for CSF shunting procedures including catheters, valves, reservoir devices, connectors and accessories to aid in implantation.

A shunt system may comprise of a catheter, valve, reservoir and connectors, depending on clinician preference and use. In practice, a catheter is implanted into the space where CSF drainage is necessary (ventricles of the brain or lumbar subarachnoid space) and connected to a valve. The valve is used to control the CSF drainage rate. The other side of the valve is connected to a catheter which is placed to allow drainage to the desired site, typically the right atrium of the heart or the peritoneal cavity. As needed, a clinician may also incorporate a reservoir, for a closed ventricular access site, and/or additional connectors into the shunt system.

Catheters are silicone elastomer and some models are made from high durometer silicone elastomer. Valve mechanisms are categorized as diaphragm and miter. For diaphragm valves, the mechanism is an umbrella shaped component oriented at right angles to the flow path. Miter valves incorporates two silicone flaps in the shape of a duckbill. The flaps part in response to a pressure differential to allow flow. Some vales are available with low, medium or high closing pressure ranges and some contain an anti-siphon component. Reservoirs are available as standard or side-inlet or convertible and in various sizes; some have an on-off flushing feature. A variety of connectors, made of

nylon or silicone elastomer material, are also available.	
807.92(a)(5) – Intended use of the device	
Indications for Use	**LPV II Valves and Kits** The Standard-LPV II and Mini-LPV II Valves, utilized in the treatment of hydrocephalic patients, are components in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. The Mini-LPV II Valve can be used in (but is not restricted to) situations where skin erosion may be a problem, as with older patients. **Novus Valves and Kits** The Novus and Novus Mini Valves, utilized in the treatment of hydrocephalic patients, are components in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. The Novus Mini Valve can be used in (but is not restricted to) situations where skin erosion may be a problem, as with older patients. Valves with a Physiological Flow Device are intended to reduce the hazard of negative intraventricular pressure (with respect to atmospheric pressure) when the patient is sitting, standing or semi-recumbent. **Multi-Purpose Valve** The Multi-Purpose Valve, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum. Valves with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing. **Mishler Dual Chamber Valve with Integral Connectors** The Mishler Dual Chamber Flushing Valve, Flat Bottom Design, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum.

	Valves with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing. **Pudenz Flushing Valve with Integral Connectors** The Pudenz Flushing Valve, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. Valves with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing. **Ultra VS In-Line Valve System** The Ultra VS In-Line Valves, utilized in the treatment of hydrocephalic patients, are components in systems designed to shunt cerebrospinal fluid (CSF) from the lateral ventricles into either the peritoneal cavity or the right atrium of the heart. The in-line and burr-hole systems are designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneal cavity. A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated. The Small and Neonate Models can be used in (but are not restricted to) situations where skin erosion may be a problem, as with premature infants, pediatric patients and older patients. **Pudenz Cardiac and Infant Catheter** The Pudenz Cardiac Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into the right atrium of the heart. The Infant Cardiac Catheter is utilized when the common facial and/or internal jugular veins are too small to accommodate the larger cardiac catheter. **Pudenz Ventricular Catheter** The Pudenz Ventricular Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the

	brain into either the right atrium of the heart or the peritoneum. **Pudenz Peritoneal Catheter** The Pudenz Peritoneal Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneum. A ventriculoperitoneal shunting system may be indicated to avoid the cardio vascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated. **Peritoneal Reflux Control Catheter and Peritoneal Open-Ended Catheter With Slits** The Peritoneal Reflux Control Catheter and Peritoneal Open-Ended Catheter with Slits, utilized in the treatment of hydrocephalic patients, are components for systems designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneum. A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated. **Portnoy Ventricular Catheter** The Portnoy Ventricular Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum. **Neuroview Endoscopic Ventricular Catheter** The Neuroview Ventricular Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum. **Integra CSF Reservoir with Integral Connectors** The Integra CSF Reservoir provides access to the lateral cerebral ventricles via hypodermic puncture for sampling and/or injection of fluids. It is useful in obtaining CSF samples for cytological and chemical studies, for monitoring

	ventricular fluid pressure and for ventricular drainage. The Convertible Integra CSF Reservoir may be utilized in hydrocephalic patients as a component in systems designed to shunt CSF from the lateral ventricles into either the right atrium of the heart or the peritoneum. **Essential Shunt Kit Burr Hole Design** The CSF Control Valve, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. **Essential Shunt Kit Flat Bottom Design** The Essential Shunt Kit – Flat Bottom Design, utilized in the treatment of hydrocephalic patients, is designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into the peritoneum. The Essential Shunt Kit – Flat Bottom Design, can be used in (but is not restricted to) situations where skin erosion may be a problem, as with older patients. **Connectors for Neurosurgical Use** Integra connectors are utilized principally in the treatment of hydrocephalic patients, as components in systems designed to shunt cerebrospinal fluid from the lateral cerebral ventricles of the brain into either the right atrium of the heart or the peritoneum. **On-Off Flushing Reservoirs** The On-Off Flushing Reservoir, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum. Reservoirs with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing. **Braden Flushing Reservoir** The Braden Flushing Reservoir, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum.

	Foltz Flushing Reservoir The Foltz Flushing Reservoir, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum. **Anti-Siphon Device** The Anti-Siphon Device, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. The device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when the patient is in a sitting, standing or erect position.

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

The proposed Integra Neurological Shunts and Accessories 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.

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

Non-clinical testing was performed to support MRI Labeling for Integra Neurological Shunts and 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 devices was 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 devices was 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°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 using both gradient and spin echo sequences. Our labeling lists the worst-case image artifact for gradient echo sequencing.

Functional testing before/after exposure to MR scanning conditions was not performed because:

- The catheters in scope are single lumen tubing that would be not be affected by exposure to MR scanning conditions.
- The mechanisms of the valves in scope do not have any metallic components and therefore would not be affected by exposure to MR scanning conditions.

The results of this testing have demonstrated that the devices listed below are MR Conditional and support the conditions as defined within the labeling:

Integra Neurological Shunts and Accessories Products
(LPV II Valves and Kits, Novus Valves and Kits,
Multi-Purpose Valve,
Mishler Dual Chamber Valve with Integral Connectors,
Pudenz Flushing Valve with Integral Connectors,
Ultra VS In-Line Valve System,
Pudenz Cardiac and Infant Catheter,
Pudenz Ventricular Catheter,
Pudenz Peritoneal Catheter,
Peritoneal Reflux Control Catheter and Peritoneal Open-Ended Catheter With Slits,
Portnoy Ventricular Catheter,
Neuroview Endoscopic Ventricular Catheter,
Integra CSF Reservoir with Integral Connectors,
Essential Shunt Kit Burr Hole Design,
Essential Shunt Kit Flat Bottom Design,
Connectors for Neurosurgical Use,
On-Off Flushing Reservoirs,
Braden Flushing Reservoir,
Foltz Flushing Reservoir,

Anti-Siphon Device)

807.92(b)(3) – Conclusions drawn from non-clinical data

The proposed Integra Neurological Shunts and Accessories, as identified within this submission, are substantially equivalent to the currently marketed Integra Neurological Shunts and Accessories, which were either previously cleared by the United States Food and Drug Administration (FDA) or were determined to be equivalent to a pre-amendment device, as outlined in the "Legally marketed device(s) to which equivalence is claimed" section of this 510(k) summary.

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 non-clinical testing has demonstrated the devices listed below are MR Conditional; a patient with these devices can be safely scanned in an MR system meeting the conditions defined within the labeling:

Integra Neurological Shunts and Accessories Products
(LPV II Valves and Kits,
Novus Valves and Kits,
Multi-Purpose Valve,
Mishler Dual Chamber Valve with Integral Connectors,
Pudenz Flushing Valve with Integral Connectors,
Ultra VS In-Line Valve System,
Pudenz Cardiac and Infant Catheter,
Pudenz Ventricular Catheter,
Pudenz Peritoneal Catheter,
Peritoneal Reflux Control Catheter and Peritoneal Open-Ended Catheter With Slits,
Portnoy Ventricular Catheter,
Neuroview Endoscopic Ventricular Catheter,
Integra CSF Reservoir with Integral Connectors,
Essential Shunt Kit Burr Hole Design,
Essential Shunt Kit Flat Bottom Design,
Connectors for Neurosurgical Use,
On-Off Flushing Reservoirs,
Braden Flushing Reservoir,
Foltz Flushing Reservoir,
Anti-Siphon Device)