



Food and Drug Administration  
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September 22, 2016

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

Re: K161992

Trade/Device Name: Horizontal-Vertical Lumbar Valve Systems, Spetzler Lumbar  
Peritoneal Shunt Systems

Regulation Number: 21 CFR 882.5550

Regulation Name: Central Nervous System Fluid Shunt and Components

Regulatory Class: Class II

Product Code: JXG

Dated: August 22, 2016

Received: August 23, 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,

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

510(k) Number (if known)  
K161992

Device Name

Horizontal-Vertical Lumbar Valve Systems, Spetzler Lumbar Peritoneal Shunt Systems

Indications for Use (Describe)

Horizontal-Vertical Lumbar Valve Systems

Horizontal-Vertical Lumbar Valve Systems are implantable devices used in the treatment of patients with communicating hydrocephalus to shunt cerebrospinal fluid (CSF) from the lumbar subarachnoid region to the peritoneal cavity. They provide controlled intraventricular pressure and CSF drainage in patients with hydrocephalus. The antechamber can be electively mounted in line with the Valve Unit to allow for CSF sampling or injections in the subarachnoid space.

Spetzler Lumbar Peritoneal Shunt Systems

Percutaneous lumbar peritoneal shunting may be utilized in the treatment of communicating hydrocephalus. It is designed to shunt CSF from the lumbar subarachnoid space to the peritoneal cavity.

The shunt may be used for diagnosis, evaluation or treatment of normal pressure communicating hydrocephalus.

A percutaneous lumbar peritoneal shunt is also useful in the management of persistent cerebrospinal fluid fistulas, bulging cranial and suboccipital decompressions and in transient CSF absorption defects, e.g. post-meningitic or post-hemorrhagic hydrocephalus.

The In-Line Valve, available as a separate component of the system, is indicated for use where added resistance is desired to alleviate symptoms of low pressure in the small percentage of patients who, after normal drainage and in the normal course of treatment, develop such symptoms.

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) substantial equivalence information in accordance with the requirements of 21 CFR 807.92

<b>807.92(a)(1) – Submitter information</b>	
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	July 18, 2016
<b>807.92(a)(2) – Name of device</b>	
Trade or Propriety Name	Horizontal-Vertical Lumbar Valve Systems Spetzler Lumbar Peritoneal Shunt Systems
Common or Usual Name	Hydrocephalus Shunts
Classification Name	Shunt, Central Nervous System And Components
Classification Panel	Neurology
Regulation	Class II, under 21 CFR 882.5550
Product Code(s)	JXG
<b>807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed</b>	
<p>Predicate device: Horizontal-Ventricular Lumbar Valves and Spetzler Lumbar Peritoneal Shunt Systems; K101381</p> <p>Reference device: Integra DP Valve Systems (Including Burr Hole Reservoirs and Stainless Steel Connectors), Gravity Compensating Accessory; K152897</p>	
<b>807.92(a)(4) - Device description</b>	

#### Horizontal-Vertical Lumbar Valve Systems

The Horizontal-Vertical Lumbar Valve System is an implantable device that provides controlled intraventricular pressure and cerebrospinal fluid (CSF) drainage from the lumbar subarachnoid region to the peritoneal cavity. The system minimizes overdrainage by automatically compensating for changes in CSF hydrostatic pressure when the patient changes from a recumbent to an upright position.

#### Spetzler Lumbar Peritoneal Shunt Systems

The Spetzler Lumbar Peritoneal Shunt Systems are designed to shunt cerebrospinal fluid (CSF) from the lumbar subarachnoid space to the peritoneum. Due to the small diameter of the catheter tubing, shunting may be accomplished by percutaneous techniques. The lumbar catheter is inserted into the lumbar subarachnoid space through a 8.89cm (3½-inch), 14- gauge Tuohy spinal needle with a Huber tip. A catheter passer and peritoneal trocar may be used to bring the peritoneal catheter section around the flank and into the peritoneal cavity.

A variety of devices are available: a one-piece model without a reservoir; separate large or small reservoirs that contain a one-way valve, which may be used when a flushing capability is required; and a separate miter valve, available in low, medium, or high pressure, which may be used when added resistance is desired.

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**807.92(a)(5) – Intended use of the device**

<p><b>Indications for Use</b></p>	<p><b><u>Horizontal-Vertical Lumbar Valve Systems</u></b></p> <p>Horizontal-Vertical Lumbar Valve Systems are implantable devices used in the treatment of patients with communicating hydrocephalus to shunt cerebrospinal fluid (CSF) from the lumbar subarachnoid region to the peritoneal cavity. They provide controlled intraventricular pressure and CSF drainage in patients with hydrocephalus. The antechamber can be electively mounted in line with the Valve Unit to allow for CSF sampling or injections in the subarachnoid space.</p> <p><b><u>Spetzler Lumbar Peritoneal Shunt Systems</u></b></p> <p>Percutaneous lumbar peritoneal shunting may be utilized in the treatment of communicating hydrocephalus. It is designed to shunt CSF from the lumbar subarachnoid space to the peritoneal cavity.</p> <p>The shunt may be used for diagnosis, evaluation or treatment of normal pressure communicating hydrocephalus.</p> <p>A percutaneous lumbar peritoneal shunt is also useful in the management of persistent cerebrospinal fluid fistulas, bulging cranial and suboccipital decompressions and in transient CSF absorption defects, e.g. post-meningitic or post-hemorrhagic hydrocephalus.</p> <p>The In-Line Valve, available as a separate component of the system, is indicated for use where added resistance is desired to alleviate symptoms of low pressure in the small percentage of patients who, after normal drainage and in the normal course of treatment, develop such symptoms.</p>
<p><b>807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate</b></p>	

The proposed Horizontal-Vertical Lumbar Valve Systems and Spetzler Lumbar Peritoneal Shunt Systems have the same technological characteristics compared to the predicate devices of the same name (K101381) as shown in the table below. The update of the MRI safety information in the labeling to increase the maximum spatial gradient and to align with the FDA’s guidance document “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment 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. This update to the labeling is consistent with that cleared under K152897, which serves as a reference device for this submission.

Technological Characteristics as Compared to Predicate of Same Name

Feature	Horizontal-Vertical Lumbar Valve Systems	Spetzler Lumbar Peritoneal Shunt Systems
Intended Use/ Indications for Use	Same – see 807.92(a)(5)	Same – see 807.92(a)(5)
Product Classification	Same – Class II	Same – Class II
Product Code	Same – JXG	Same – JXG
Design	Same – Differential pressure valve with two balls in cone valve mechanisms: a spring-actuated (lower) pressure mechanism and a gravity-actuated (higher) pressure mechanism.	Same – Pressure control is achieved through a combination of double slit valve at the peritoneal end and the small inner diameter catheter
Performance Specifications	Same – Six pressure ranges with closing pressures between 50 and 125 mmH <sub>2</sub> O in the horizontal position and between 170 and 445 mmH <sub>2</sub> O in the vertical position.	Same – Six systems with pressure ranges with closing pressures between 50 and 400 mmH <sub>2</sub> O
MRI Status	Same – MR Conditional	Same – MR Conditional
Sterilization	Same - Ethylene Oxide/ SAL = 10 <sup>-6</sup>	Same - Ethylene Oxide/ SAL = 10 <sup>-6</sup>
Biocompatible	Same – Yes	Same – Yes
Non-Pyrogenic	Same – Yes	Same – Yes
Packaging	Same – sterile, double packaged system	Same – sterile, double packaged system

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

No additional non-clinical testing was performed for this submission. Non-clinical testing was performed to support the initial MRI Labeling for Integra Shunts and Implanted Accessories, which was cleared under K101381. Testing included:

- Magnetically Induced Displacement Force and Torque Test
- RF Heating Test
- Image Artifact Test
- Pressure Flow Test

The non-clinical testing has since been amended to include updated calculations for the maximum spatial gradient based on ASTM F2052-15 and clinical injury threshold considerations, which were cleared under K152897.

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

The proposed Horizontal-Vertical Lumbar Valve Systems and Spetzler Lumbar Peritoneal Shunt Systems are substantially equivalent to the currently marketed Horizontal-Vertical Lumbar Valve Systems and Spetzler Lumbar Peritoneal Shunt Systems which were previously cleared to market by the United States Food and Drug Administration (FDA) on July 7, 2011 under K101381.

The update of the 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.