K101381

INTEGRA
LIMIT UNCERTAINTY

510(k) Summary

JUL - 7 2011

1. Contact Details

Applicant Name: Integra LifeSciences Corporation
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Date Prepared: June 23, 2011

2. Device Name

Tradename: Horizontal-Vertical Lumbar Valve Systems
Spetzler™ Lumbar Peritoneal Shunt Systems

Common Name: Hydrocephalus Shunts

Classification Name: Shunt, Central Nervous System and Components, JXG

3. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K944595	JXG	Cordis Horizontal-Vertical Valve System	Integra LifeSciences (Previously Cordis Corp.)
K811288	JXG	Spetzler Lumbar-Peritoneal Systems	Integra LifeSciences (Previously American Heyer-Schulte Corp.)
K871685	JXG	Heyer-Schulte Spetzler Lumbar-Peritoneal Shunt Systems	Integra LifeSciences (Previously American Heyer-Schulte Corp.)

4. Device Description

The Horizontal-Vertical Lumbar Valve and the Spetzler Lumbar-Peritoneal Shunt 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. Both are differential pressure valves designed to open when the difference between ventricular or lumbar pressure and outlet cavity pressure exceeds a certain threshold.

The primary issues affecting the safety and compatibility of passive implants in the MR environment concern magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts. The addition of MRI Safety information to the labeling is intended to provide for safe use of the shunt systems by clarifying the conditions required to safely use these devices in an MR environment in a readily available, clear and concise manner, to healthcare providers.

5. Intended Use/Indications for use

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. The Spetzler Shunt systems are 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.

6. Substantial Equivalence Comparison

The Horizontal-Vertical Lumbar Valve and the Spetzler Lumbar-Peritoneal Shunt systems are identical to currently marketed predicate Horizontal-Vertical Lumbar Valve and Spetzler Lumbar-Peritoneal Shunt systems except for a labeling revision to add MRI safety information for the safe use of the devices in an MR environment.

Feature	Predicate Horizontal-Vertical Lumbar Valve System (K944595)	Horizontal-Vertical Lumbar Valve System
Indications for Use	Implantable system used in the treatment of patients with communicating hydrocephalus, to shunt CSF from the lumbar subarachnoid region to the peritoneal cavity.	**Same as Predicate Horizontal-Vertical Lumbar Valve System**
Incorporates the same basic design and utilizes the same operating principle	Differential pressure valve with two balls in cone valve mechanisms: a spring actuated (lower) pressure mechanism and a gravity-actuated (higher) pressure mechanism. Flow direction identified by an arrow on the stainless steel modulus	**Same as Predicate Horizontal-Vertical Lumbar Valve System**
Performance Specifications	Six pressure ranges with closing pressures between 50 and 125 mmH_20 in the horizontal position and between 170 and 445 mmH_20 in the vertical position.	**Same as Predicate Horizontal-Vertical Lumbar Valve System**
MRI Safe	Integra NeuroSciences tests indicate that MRI exposure does not affect pressure valve settings. No significant forces or temperature changes were noticed during MRI exposure.	**MR Conditional**
Biocompatible	Yes	**Same as Predicate Horizontal-Vertical Lumbar Valve System**

Feature	Predicate Spetzler Lumbar Peritoneal Shunt Systems (K811288 and K871685)	Spetzler Lumbar Peritoneal Shunt Systems
Indications for Use	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.	**Same as Predicate Spetzler Lumbar Peritoneal Shunt Systems**
Incorporates the same basic design and utilizes the same operating principle	Pressure control is achieved through a combination of the double slit valve at the peritoneal end and the small inner diameter catheter	**Same as Predicate Spetzler Lumbar Peritoneal Shunt Systems**
Performance Specifications	Six systems with pressure ranges with closing pressures between 50 and 400 mmH_20	**Same as Predicate Spetzler Lumbar Peritoneal Shunt Systems**
MRI Safe	No claim	**MR Conditional**
Biocompatible	Yes	**Same as Predicate Spetzler Lumbar Peritoneal Shunt Systems**

7. Non-Clinical Testing

The Horizontal-Vertical Lumbar Valve Systems and Spetzler Lumbar Peritoneal Shunt Systems are identical in design, performance, and materials of composition to the currently marketed predicate systems. Since the proposed shunts and accessories are identical to the currently marketed shunts and accessories, all performance testing relating to the performance of the predicate devices also supports the proposed devices, and remains unchanged. Additional bench testing was performed to determine the safe use conditions for these products in the MR environment, as described below. Testing was also performed to confirm that the performance of these devices remains the same after use in an MR environment.

DESIGN VERIFICATION TEST	Acceptance
Visual Inspection	All test samples shall be complete and free of visible damage.
Magnetically Induced Displacement Force Test **ASTM F2052**	The amount of magnetically induced force on the device shall be less than or equal to the force on the device due to gravity.
Magnetically Induced Torque Test **ASTM F2213**	The amount of magnetically induced torque on the device shall be less than or equal to the gravitational torque.
RF Heating Test **ASTM F 2182**	No portion of the implanted device shall exhibit an increase in temperature of more than 2°C at a SAR of 2W/kg.
Image Artifact Test **ASTM F2119**	There is no acceptance criterion as per ASTM standard; this test is performed to gather information relating to image artifacts caused by the device. This information can be included in labeling.

The non-clinical testing has demonstrated that the Horizontal-Vertical Lumbar Valve Systems and Spetzler Lumbar Peritoneal Shunt Systems are MR Conditional, as defined in the ASTM 2503-05 Standard, "*Standard Practice for Marking Medical Devices and other items for Safety in the Magnetic Resonance Environment.*" This classification is appropriate for "an item which has been demonstrated to pose no known hazards in specific MR environment with specified conditions.

8. Clinical Testing

Clinical testing was not applicable for this modification.

9. Conclusions

The conclusions drawn from the nonclinical testing demonstrate that both the Horizontal-Vertical Lumbar Valve Systems and the Spetzler Lumbar Peritoneal Shunt Systems, with the addition of MRI Safety information in the labeling, are as safe and effective, and perform at least as safely and effectively, as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Integra Life Sciences Corporation
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Manager, Corporate Regulatory Affairs
311 Enterprise Drive
Plainsboro, NJ 08536

JUL - 7 2011

Re: K101381
Trade/Device Name: Integra Horizontal-Vertical Lumbar Valve Systems and 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: May 9, 2011
Received: May 10, 2011

Dear Ms. Millisky:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K10138/

Device Name: Horizontal-Vertical Lumbar Valve Systems

Indications for Use:

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.

Prescription Use ___X___ **AND/OR** **Over-The-Counter-Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K10138/

INDICATIONS FOR USE STATEMENT

510(k) Number: K101381

Device Name: Spetzler™ Lumbar Peritoneal Shunt Systems

Indications for Use:

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.

Prescription Use ___X___ **AND/OR** **Over-The-Counter-Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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