K092395

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name and Address:

NOV 19 2009

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Date Summary was Prepared: July 31, 2009

Name of the Device:

Trade Names:	OSV II® Lumbar Valve System OSV II® Low Flow Lumbar Valve System
Common Name:	Central Nervous System Fluid Shunt and Components
Classification Name:	Hydrocephalus Valve
Product Code:	JXG
Classification Panel:	Neurology

Device Description:

The OSV II® Lumbar Valve System (OSV II Valve) and the OSV II® Low Flow Lumbar Valve System (OSV II Low Flow Valve) are implantable devices for controlled cerebrospinal fluid drainage (CSF) from the lumbar subarachnoid region to the peritoneal cavity. Unlike conventional valves, they are variable resistance valves which maintain a drainage rate constant within the physiological range (for the specified populations and disorders) of intracranial pressure. They maintain a drainage rate around 20ml/hr for OSV II Valves and around 10ml/hr for OSV II Low Flow Valves.

The OSV II Lumbar Valve System and OSV II Low Flow Lumbar Valve System are provided with accessories including a 14G tuohy needle, a F5 lumbar catheter, a guidewire, a luer lock connector and a F8-F5 stepdown connector, which are required for using the valves in a lumbar approach. The designs of the accessories are identical to the accessories currently provided with the Integra H-V Lumbar Valve System.

Indications for Use:

Both the OSV II Lumbar Valve System and the OSV II Low Flow Lumbar Valve System are indicated as implantable systems used in the treatment of patients with communicating hydrocephalus to shunt CSF from the lumbar subarachnoid region to the peritoneal cavity.

Principle of Operation:

The Principle of Operation of both the OSV II Lumbar Valve System and OSV II Low Flow Lumbar Valve System are as follows:

The variable flow restrictor consists of a silicone elastomer diaphragm, synthetic ruby seat, and notched pin. The diaphragm reacts to differential pressure (DP) variations. The seat is inserted into the center of the diaphragm. As differential pressure varies, the clearance between the seat and the pin increases or decreases depending on seat movement along the pin. Changes in the seat and pin clearance vary flow rates.

Note – Differential pressure/flow characteristics for each valve are verified to be within specification at time of manufacture.

The three stages of operation of the OSV II® Lumbar Valve System and the OSV II® Low Flow Lumbar Valve System are defined below:

Stage I – Low Differential Pressure
This stage begins when the flow rate through the valve reaches 5ml/hr (DP will be between 30 and 80 mm H_20). The valve remains in Stage I with CSF flow rates up to 18 ml/hr (up to 8 ml/hr for the OSV II Low Flow) (DP will be between 40 and 120 mm and 120 mm H_20).

Stage II – Flow Regulation
When the DP increases, the valve operates as a variable resistance flow regulator. At DP ranges between 120 and 300 mm H_20, the valve restricts flow between 18 and 30 ml/hr (between 8 and 17 ml/hr for the OSV II Low Flow).

Stage III – Pressure Relief Mode
Should the intraventricular pressure (IVP) elevate abruptly, the shunt operates in a rapid flow rate mode to facilitate IVP normalization. The valve then reverts to Stage II or I, depending upon conditions.

Materials:

The materials of composition for both the OSV II Lumbar Valve System and OSV II Low Flow Lumbar Valve System are identical: silicone elastomer with or without barium sulfate, polysulfone, synthetic ruby, silicone adhesive, tantalum, polypropylene and epoxy.

The accessories include a lumbar catheter and suture clamp made of silicone elastomer with

barium sulfate. The guidewire used to introduce the catheter is made of stainless steel, coated with polytetrafluoroethylene (PTFE), the stepdown connector is made of polypropylene with barium sulfate and the luer connector (to flush catheter) is made of polycarbonate. The 14G tuohy needle is made of stainless steel, with polycarbonate wings. The materials used in the accessories are identical to those materials used in the the H-V Lumbar Valve accessories, except the F8-F5 stepdown connector is made of stainless steel in the H-V Lumbar Valve and is made of polypropylene with barium sulfate for the proposed OSV II and OSV II Low Flow valves. The current OSV II and Integra NPH Low Flow Valve systems already provide straight connectors made of the same polypropylene with barium sulfate and a lumbar catheter made with silicone elastomer.

Substantial Equivalence:

The proposed OSV II and OSV II Low Flow Valves are substantially equivalent in function to the currently approved OSV II and Integra NPH Low Flow Valve Systems cleared to market by FDA under K971799, K081773, and K042192. This bundled 510(k) supports the use of both valve systems using a lumbo-peritoneal approach. The accessories provided allow for a lumbar approach and are substantially equivalent to the accessories provided with the Integra H-V Lumbar Valve System, which was cleared by FDA under K944595 for the same intended use. These accessories include a 14G tuohy needle, F5 lumbar catheter, guidewire, stepdown connector, and suture clamp.

The OSV II Lumbar Valve System and OSV II Low Flow Lumbar Valve System are designed the same as the valves currently used with the OSV II and Integra NPH Low Flow Valve Systems provided for the ventricular approach. Since the valves are the same, the product and performance specifications are the same as the predicate valves.

The Principle of Operation, intended use, design, materials of composition and manufacturing processes for both the OSV II Lumbar Valve System and OSV II Low Flow Lumbar Valve System are the same as for the current OSV II and Integra NPH Low Flow hydrocephalus valves. The labeling has been revised to include the indications for treatment of patients with communicating hydrocephalus to shunt CSF from the lumbar subarachnoid region to the peritoneal cavity. Based upon the stated information and supported by the clinical evidence included in this 510(k), Integra concludes that both systems are equivalent to the predicates defined in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Integra LifeSciences Corporation
c/o Ms. Donna Millisky
Regulatory Associate II
311 Enterprise Drive
Plainsboro, NJ 08536

NOV 19 2009

Re: K092395
Trade/Device Name: OSV II® Lumbar Valve System, OSV II® Low Flow Lumbar Valve System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: II
Product Code: JXG
Dated: October 23, 2009
Received: October 26, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

K092395

INDICATIONS FOR USE STATEMENT

510(k) Number: K092395

Device Name: OSV II Lumbar Valve System

Indications for Use:

The OSV II® Lumbar Valve System is an implantable system used in the treatment of patients with communicating hydrocephalus to shunt CSF from the lumbar subarachnoid region to the peritoneal cavity.

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

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

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

510(k) Number K092395

K092395

INDICATIONS FOR USE STATEMENT

510(k) Number: K092395

Device Name: OSV II® Low Flow Lumbar Valve System

Indications for Use:

The OSV II® Low Flow Lumbar Valve System is an implantable system used in the treatment of patients with communicating hydrocephalus to shunt CSF from the lumbar subarachnoid region to the peritoneal cavity.

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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