K093968

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 22 2010

Submitter's Name and Address:

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Date Summary was Prepared: December 22, 2009

Name of the Device:

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

Device Description:

The proposed OSV II Low Flow Low Pro Valve (OSV II LFLP) and the currently marketed Integra NPH Low Flow Valve System (NPH Valve) are implantable hydrocephalus valve systems for shunting controlled cerebrospinal fluid (CSF) drainage from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium. Unlike conventional valves, these valves are variable resistance valves which maintain a drainage rate constant within the physiological range for the specified populations and disorders of intracranial pressure. These valves were designed to maintain a lower drainage rate than that of normal CSF production (approximately 20 ml/hr), and are intended to accommodate the needs of patients requiring a drainage rate between 8-17 ml/hr. The proposed OSV II LFLP Valve is designed to maintain the same lower drainage rate of 8-17 ml/hr, but with a smaller overall height and diameter to accommodate the needs of patients requiring a smaller valve.

The proposed OSV II Low Flow Low Pro Valve (OSV II LFLP) is similar to the currently

marketed Integra NPH Low Flow Valve. The proposed valve is designed to maintain the same lower drainage rate of 8-17 ml/hr, but with a smaller overall height and diameter to accommodate patients requiring a smaller valve. The modifications include a reduction in the silicone boot (external envelope) and replacement of the needle stop.

Indications for Use:

The Indications For Use for the proposed OSV II Low Flow Low Pro Valve are:

> The OSV II Low Flow Low Pro Valve is an implantable system used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.

The proposed OSV II LFLP Valve System is available in different configurations in order to accommodate the needs of the patient. A system typically consists of a valve unit, a ventricular (proximal) catheter, and a drainage (distal) catheter. Depending on the configuration, the ventricular catheter is fully radiopaque with radiopaque length markings at 2cm intervals from the tip, or, with a barium stripe and non radiopaque length markers every 1cm. Connectors are designed for use with 1.1 to 1.4 mm inner diameter silicone elastomer tubing.

Substantial Equivalence:

The proposed OSV II Low Flow Low Pro Valve is substantially equivalent to the currently marketed NPH Valve, which was cleared to market by the United States Food and Drug Administration on September 2, 2004 under K042192. The only differences between the proposed valve and the NPH Valve are the silicone boot (external envelope) and the needle stop. The proposed silicone boot is identical to the current silicone boot in the NPH Valve, but smaller in height and diameter. The needle stop was replaced with a smaller needle stop, which is substantially equivalent to the needle stop used in the currently marketed Contour-Flex Valve System cleared to market by FDA on December 17, 2003 under K033698.

The proposed OSV II LFLP Valve and the NPH Valve are identical in principal of operation, performance specifications, materials of composition, technology, manufacturing and sterilization processes, and packaging. The designs are the same, except that the proposed OSV II LFLP Valve profile is smaller. The current NPH labeling has been revised to reflect the proposed device. The needle stop of the proposed OSV II LFLP and the needle stop of the current Contour-Flex Valve are identical in design, materials, intended use, body contacts and duration of use. The proposed modifications do not change the Indications for Use, the intended use, or the fundamental scientific technology of the devices and they do not raise new issues of safety and effectiveness.

The proposed OSV II LFLP is substantially equivalent to the current NPH Valve (K042192); and the proposed needle stop feature is substantially equivalent to the current needle stop feature of the Contour-Flex Valve (K033698).

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

JAN 22 2010

Re: K093968
Trade/Device Name: OSV II® Low Flow Low Pro Valve (Models: 909500P, 909512P, 90S512P, 90S502P)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: II
Product Code: JXG
Dated: December 22, 2009
Received: December 23, 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.

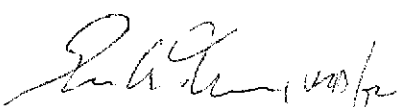
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

K093968

INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: OSV II® Low Flow Low Pro Valve

Indications for Use:

The OSV II® Low Flow Low Pro Valve is an implantable system used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.

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 K093968