K081773

**OSVII Hydrocephalus Valve**
**510(k) SUMMARY**

**Submitter's name and address:**

Integra NeuroSciences Implants SA
2905 Route des Dolines
06921 Sophia Antipolis Cedex, France

NOV - 6 2008

**Contact person and telephone number:**

Anne Bigeard
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**Date summary was prepared:**

June 10, 2008

**Name of the device:**

| | |
|---|---|
| Proprietary Name: | OSVII Hydrocephalus Valve |
| Common Name: | Hydrocephalus Shunt Systems and Components |
| Classification Name: | Central Nervous System Shunt and Components JXG |

**Substantial Equivalence:**

The modified OSV II is substantially equivalent to the OSV II cleared by the FDA under 510(k) (K911799). The design, principle of operation, intended use, materials of composition, manufacturing process is equivalent to the previously cleared OSV II.

**Intended use:**

The OSVII 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.

**Device Description:**

The OSV II is designed to shunt cerebrospinal fluid (CSF) from the ventricles of the brain to an appropriate drainage site, such as the atrium of the heart or the peritoneal cavity. Unlike conventional valves, it is a variable resistance valve which maintains a drainage rate constant within the physiological range (for the specified populations and disorders) of intracranial pressure.

The principle of operation consists of a flow restricting diaphragm, a seat, and a notched pin. The diaphragm, held between two polysulfone parts of the casing, reacts to variations in pressure. A synthetic ruby seat is inserted into the center of the diaphragm. As pressure varies, the clearance between the seat and the pin increases or decreases depending on seat movement along the pin.

Three Stages of Operation are defined:

***Stage I - Low Differential Pressure***
This stage begins when the flow rate through the valve reaches 5ml/hr (Differential Pressure (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 (DP will be between 40 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.

***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.

**Safety and Effectiveness:**

- The OSV II Hydrocephalus Valve is provided sterile and non-pyrogenic.
- The correlation established between the unmodified and modified test methods demonstrated that the modification did not adversely affect the safety or effectiveness of the product.
- The connector modification to the OSV II had been tested for leakage and for resistance of the connections at time of manufacturing, after shelf life simulation and after transport and environmental conditions.

**Conclusion:**

The modified OSV II is considered substantially equivalent to the unmodified OSV II cleared by the FDA under 510(k) (K911799). The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2008

Integra LifeSciences Corporation
% Mr. Jon Caparotta, RAC
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K081773
Trade/Device Name: OSV II
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: October 2, 2008
Received: October 7, 2008

Dear Mr. Caparotta:

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.

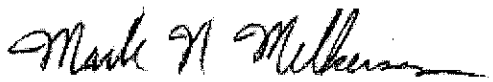
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): **K081773**

Device Name: **OSV II**

Indications For Use:

The OSV II 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) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxa

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K081773