K042192 1/2

Low Flow OSVII Hydrocephalus Valve

SEP - 2 2004

510(k) SUMMARY

Submitter's name and address:

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Contact person and telephone number:

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Date summary was prepared:

August 11, 2004

Name of the device:

Proprietary Name:	Low Flow 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 (Low flow OSV II) Hydrocephalus Valve is substantially equivalent in function and intended use to the unmodified OSVII (Precision flow OSV II) Hydrocephalus Valve which has been cleared to market under Premarket Notification 510(k) K971799.

Intended use:

The Low Flow OSV II Hydrocephalus 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.

Device Description:

The Precision Flow OSV II and the modified Low Flow OSV II hydrocephalus valve systems are implantable devices for controlled cerebrospinal fluid drainage from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium. 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.

Safety

The Low Flow OSV II Hydrocephalus Valve and the Precision Flow OSV II Hydrocephalus Valve are provided sterile and non-pyrogenic. Performance testing has been performed on The Low Flow OSV II Hydrocephalus Valve reflecting shelf life simulation and environmental conditions. A review of clinical experiences and of published scientific

literature supports the rationale for this additional flow regulation rate which is designed to address the needs of patients who require a lower drainage rate.

Conclusion

The Low Flow OSV II Hydrocephalus Vavle is substantially equivalent to the Precision Flow OSV II Hydrocephalus Valve. 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. The design, materials of composition and principle of operation of the Low Flow OSV II Hydrocephalus Valve and the Precision Flow OSV II Hydrocephalus Valve remain the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Integra NeuroSciences Implants, S.A.
c/o Ms. Judith E. O'Grady
Sr. Vice President Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K042192
Trade/Device Name: Low Flow OSV II Hydrocephalus Valve
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: August 11, 2004
Received: August 12, 2004

Dear Ms. O'Grady:

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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K042192

Device Name: Low Flow OSV II

Indications For Use:

The Low Flow 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K042192