K032817

OCT - 6 2003

External Drainage Set

510(k) SUMMARY

Submitter's Name and Address:

Integra NeuroSciences Implants S.A.
2905 Route des Dolines
06921 Sophia Antipolis
Cedex, France

Contact Person and Telephone Number:

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Integra NeuroSciences Implants S.A.
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Authorized Agent in the United States:

Judith E. O'Grady
Integra LifeSciences Corporation
Sr. Vice President Regulatory, Quality and Clinical Affairs
311 Enterprise Drive
Plainsboro, NJ 08536, USA
Telephone: 609-936-2311

Date Summary was Prepared:

September 9, 2003

Name of Device:

Proprietary Name:	External Drainage Set
Common Name:	External CSF Drainage Systems
Classification Name:	Central Nervous System Shunts and Components JXG

Substantial Equivalence:

The External Drainage Set is substantially equivalent in function and intended use to the Unmodified External Drainage Set which has been cleared to market under Premarket Notification 510(k) K910853.

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Intended Use:

The External Drainage Sets are intended for cerebrospinal fluid (CSF) drainage, sampling and collection.

Device Description:

The External Drainage Set is designed for cerebrospinal fluid (CSF) drainage, sampling and collection. The system connects to a ventricular or lumbar catheter via a Luer connection to a patient line.

The graduated cylinder of the External Drainage Set is attached to an IV pole and may be moved up and down to change positioning of the graduated cylinder by using the Velcro straps. CSF can be collected and measured in the graduated cylinder and subsequently emptied to the drainage bag by opening the stopcock placed in-line between the graduated cylinder and the drainage bag.

A hydrophobic vent filter is included in the graduated cylinder cap of the External Drainage Set. This vent filter allows air to enter the graduated cylinder to facilitate drainage from the graduated cylinder to the drainage bag while protecting the system from contamination.

Safety:

The External Drainage Set is provided sterile. The External Drainage Set has been tested for tensile strength of bonded components, pressure and leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids in compliance with the Needlestick Safety and Prevention Act, H.R.5178.

Conclusion:

The External Drainage Set is substantially equivalent to the unmodified External Drainage Set. 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

OCT - 6 2003

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

Re: K032817
Trade/Device Name: External Drainage Set
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: September 9, 2003
Received: September 11, 2003

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,

for Miriam C. Provost

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 STATEMENT

510(k) Number: K032817

Device Name: External Drainage Set

Indications for Use:

The drainage sets are intended for cerebrospinal fluid (CSF) drainage, sampling and collection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____
(Per 21 CFR 801.109

Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032817