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AccuDrain™ External CSF Drainage System

510(k) SUMMARY

Submitter's Name and Address:

Integra LifeSciences Corporation
(d/b/a Integra NeuroSciences)
311 Enterprise Drive
Plainsboro, NJ 08536

Contact Person and Telephone Number:

Darlene M. Welsh, RAC
Sr. Regulatory Project Manager
Telephone: (609) 275-0500
Facsimile: (609) 275-9445

Date of Summary:

October 7, 2004

Name of the Device:

Proprietary Name:	AccuDrain™ External CSF Drainage System
Common Name:	External CSF Drainage System
Classification Name:	Central Nervous System Shunt and Components JXG

Substantial Equivalence:

The AccuDrain™ External CSF Drainage System is substantially equivalent in function and intended use to the Hermetic Plus™ External CSF Drainage System, Integra NeuroSciences External Drainage Set (EDS) and the Codman® External Drainage System (EDS^{3}™).

Intended Use:

The AccuDrain™ External CSF Drainage System is indicated for draining and monitoring of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), monitor intracranial pressure, to monitor cerebrospinal fluid, and provide temporary CSF drainage for patients with infected hydrocephalic shunts.

Device Description:

The AccuDrain™ External Drainage Systems are designed to externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients. The systems connect to a ventricular or lumbar catheter via a luer connection to a patient line and ultimately to a drainage bag. The patient line is connected to a graduated burette that is then connected to the drainage bag. CSF can be collected and measured in the burette and subsequently emptied into the drainage bag by opening the stopcock placed in line between the burette and the drainage bag. An antimicrobial vent is included in the burette cap. This antimicrobial vent allows air to enter the burette to facilitate drainage from the burette to the drainage bag while protecting the system from microbial contamination. The antimicrobial vent used on the AccuDrain™

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systems will allow better drainage of the CSF to the drainage bag and will resist occlusion after contact with CSF.

Safety

The AccuDrain™ External CSF Drainage Systems have been demonstrated to be MR safe* when used in the Magnetic Resonance (MR) environment.

*MRI safe is defined by the CDRH Magnetic Resonance Working Group (Feb. 7, 1997) draft document A Primer on Medical Device Interactions with MRI Systems as "The device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information."

Testing has shown that the antimicrobial vent is resistant to occlusion after 30 minutes of exposure to fluids with high protein levels. The systems have been tested for strength of bonded components, leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids.

Conclusion

The AccuDrain™ External CSF Drainage System is substantially equivalent to Hermetic Plus™ External CSF Drainage Systems, Integra NeuroSciences External Drainage Set (EDS) and the Codman® External Drainage System (EDS^{3}™).

The design of the AccuDrain™ External CSF Drainage System does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Ms. Darlene M. Welsh
Senior Regulatory Project Manager
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K042825
Trade/Device Name: AccuDrain™ External CSF Drainage System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: November 18, 2004
Received: November 23, 2004

Dear Ms. Welsh:

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 (240) 276-0115. 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 STATEMENT

510(k) Number (if known): **K042825**

Device Name: AccuDrain™ External CSF Drainage System

Indications for Use:

Draining and monitoring of Cerebrospinal Fluid (CSF) flow from the ventricles of the brain or lumbar subarachnoid space is indicated in selected patients to:

- Reduce Intracranial Pressure (ICP)
- Monitor Intracranial Pressure (ICP)
- Monitor Cerebrospinal Fluid (CSF)
- Provide temporary CSF drainage

Miriam C. Provost

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

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Prescription Use X (Part 21 CFR 801 Subpart D)

Or

Over-the-Counter Use ____ (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)