k072929

LimiTorr™ Volume Limiting External CSF Drainage and Monitoring Systems

510(k) SUMMARY

Submitter's name and address:

Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536

DEC - 7 2007

Contact person and telephone number:

Darlene M. Welsh, RAC
Manager, Regulatory Affairs
Telephone: 609-936-2307
Facsimile: 609-275-9445

Date summary was prepared:

October 15, 2007

Name of the device:

Proprietary Name:	LimiTorr™ Volume Limiting External CSF Drainage and Monitoring Systems
Common Name:	External Cerebrospinal Fluid Drainage and Monitoring System
Classification Name:	Central Nervous System Shunt and Components JXG

Substantial Equivalence:

The LimiTorr™ Volume Limiting External CSF Drainage and Monitoring Systems are substantially equivalent in function and intended use to the unmodified MoniTorr™ External CSF Drainage and Monitoring Systems which have been cleared to market under Premarket Notification 510(k) K022554.

Intended use:

The LimiTorr™ Volume Limiting External CSF Drainage and Monitoring Systems allow for drainage and monitoring of CSF from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF in patients with infected CSF shunts, and the monitoring of ICP.

Device Description:

The LimiTorr™ Volume Limiting External CSF Drainage and Monitoring 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. In most of the systems, 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.

These systems are designed for single use only.

Safety

The Limitorr™ Volume Limiting External CSF Drainage and Monitoring Systems include a mechanism designed to limit the volume of CSF colleted to a nominal volume. The volume limiting mechanism consists of a valve mounted to the top of the float that rises as the fluid collects in the burette and seals when the nominal volume is reached

The systems have been tested for strength of bonded components, leakage, drainage, sealing mechanism performance and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids.

Conclusion

The LimiTorr™ Volume Limiting External CSF Drainage System is substantially equivalent to the unmodified MoniTorr ICP™ system. These modifications do not affect the intended use, the fundamental scientific technology of the device and doe 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

DEC - 7 2007

Integra Lifesciences Corporation
% Ms. Darlene M. Welsh, RAC
Manager, Regulatory Affairs
311C Enterprise Drive
Plainsboro, New Jersey 08536

Re: K072929
Trade/Device Name: LimiTorr™ Volume Limiting External Drainage and Monitoring Systems
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: November 15, 2007
Received: November 16, 2007

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 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 STATEMENT

510(k) Number: K072929

Device Name: LimiTorr™ Volume Limiting External Drainage and Monitoring Systems

Indications for Use: The LimiTorr™ Volume Limiting External Drainage and Monitoring Systems allow for drainage and monitoring of CSF from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF in patients with infected CSF shunts, and to monitor ICP.

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)

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

510(k) Number K072929