K062499

MoniTorr ICP™
External CSF Drainage and Monitoring Systems

510(k) SUMMARY

SEP 27 2006

Submitter's name and address:

Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Contact person and telephone number:

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

Date summary was prepared:

August 30, 2006

Name of the device:

Proprietary Name:	MoniTorr ICP™ 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 MoniTorr ICP™ 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)'s K920156 and K022554.

Intended use:

The MoniTorr ICP™ 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.

The Integra Pole Mount Assemblies are utilized with the MoniTorr ICP™ External Drainage and Monitoring Systems to provide support and alignment on an I.V. Pole.

Device Description:

The Integra Pole Mount Assembly has been modified to include a line level and a laser level. The MoniTorr ICP™ External CSF Drainage and Monitoring Systems can be used

with a pole mount assembly. The Integra Pole Mount Assemblies are designed provide support and alignment to the MoniTorr ICP™ External CSF Drainage and Monitoring Systems on an I.V. Pole. The Integra Pole Mount Assemblies are designed to be reusable. The reusable Integra Pole Mount Assembly is comprised of a graduated rail with a grooved profile to support the sliding bracket which facilitates setting the pressure level while using the disposable external drainage system. The Pole Mount Assembly is aligned with the patient's anatomical reference point by using a pointer, line level or laser.

The MoniTorr ICP™ 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. In systems with this burette, 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. These systems are designed for single use only.

Safety

The Integra Pole Mount Assemblies are accessories for the MoniTorr ICP™ External CSF Drainage and Monitoring Systems. Alignment can be achieved through the use of a line level or laser level. The laser level is a Class II Laser and complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50 dated July 26, 2001.

The laser is fully compliant with the following standards:

BS EN 60601-1-2 (1993)
EN 60601-1-2 (2003)
EN 61000-4-2 (1995)
EN 61000-4-3 (1996) above 1 GHz
EN 61000-4-8 (1993)
in accordance with EN 60601-1-2 (2001)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2006

Integra NeuroSciences
% Darlene M. Welsh, RAC
Senior Regulatory Affairs Project Manager
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K062599
Trade/Device Name: MoniTorr ICP™ External Drainage and Monitoring System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt components
Regulatory Class: Class II
Product Code: JXG
Dated: August 31, 2006
Received: September 1, 2006

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

K062599

INDICATIONS FOR USE STATEMENT

510(k) Number: K062599

Device Name: MoniTorr ICP™ External CSF Drainage and Monitoring Systems

Indications for Use:

The MoniTorr ICP™ 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 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)

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

510(k) Number K062599