K022554

MoniTorr ICP™
External CSF Drainage and Monitoring System

510(k) SUMMARY

Submitter's name and address:

Integra NeuroSciences
309 Commerce Drive
Exton, PA 19341

Contact person and telephone number:

Donna R. Wallace
Director, Regulatory Affairs
(609) 275-0500

Date summary was prepared:

August 1, 2002

Name of the device:

Proprietary Name:	MoniTorr ICP™ External CSF Drainage and Monitoring System
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 System is substantially equivalent in function and intended use to the unmodified MoniTorr™ External CSF Drainage and Monitoring System which has been cleared to market under Premarket Notification 510(k) K920156.

Intended use:

The MoniTorr ICP™ system allows 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 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 subsequestly 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. The antimicrobial vent used on the current MoniTorr ICP™ systems is being replaced with a vent that will allow better drainage of the CSF to the drainage bag and will better resist occlusion after contact with CSF. The antimicrobial media chosen for the vent is not compatible with the current method of sterilization, therefore, an alternate sterilization method, ethylene oxide has been chosen to sterilize the entire line of MoniTorr ICP™ systems. A vented cap will be used in place of the current closed end cap to allow flow of gas through the patient line.

Additionally, the fluid path from the burette to the drainage bag has been enlarged and the current sampling sites are being replaced with needleless sampling sites.

Safety

The MoniTorr ICP™ External CSF Drainage and Monitoring Systems have been shown to be sterile and non-pyrogenic. Testing has shown that the antimicrobial vent is resistant to occlusion after 30 minutes of exposure to fluids with high protein levels. The antimicrobial media was subjected to an aerosol challenge with *B.diminuta* yielding a microbial retention of 10^7. The MoniTorr ICP™ systems have 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 MoniTorr ICP™ External CSF Drainage and Monitoring System is substantially equivalent to the unmodified MoniTorr ICP™ system. 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

AUG 23 2002

Integra NeuroSciences
Donna R. Wallace
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K022554
Trade/Device Name: MoniTorr ICP™ External CSF Drainage and Monitoring System
Regulation Number: 882.5550
Regulation Name: Central Nervous System Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: August 1, 2002
Received: August 2, 2002

Dear Ms. Wallace:
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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Mark N Milhern

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: K022554

Device Name: MoniTorr ICP™ External Drainage and Monitoring Systems

Indications for Use:

The MoniTorr ICP™ system allows 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.

(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)

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

C001 510(k) Number K022554