K041838

MAR 1 - 2005

Section 2.0 510(k) Summary

2.1 Submitted by

InnerSpace
Phone 949 752 8672 FAX 949 752 8673
2293 South Pullman Street, Suite A
Santa Ana, CA. 92705
Contact: Donald E. Bobo ext 12

2.2 **MPS- Oxiport** is a system capable of draining CSF, sensing ICP and receiving two monitoring probes such as oxygen or temperature. MPS stands for Multiple Parameter System.

The system consists of bolt, a bolt insert and a ventricular catheter. A slidable insert is mounted on the proximal end of the catheter at the factory. After the catheter is situated in a ventricle, the insert is moved down the catheter and into the throat of the bolt. The insert has an o-ring that forms a seal with the bolt. It also has two guide tubes. The guide tubes allow the surgeon to place probes such as an oxygen or temperature sensor in the brain.The insert has a fixation element that joins the insert to the bolt and three pigtails with Toughy-Borst fittings to fix the monitoring probes and the ventricular catheter to the insert.

2.2 ICP Monitoring Device Name

Trade name	MPS- Oxiport
Common name	Intracranial Pressure Monitoring Device
Classification name	Intracranial Pressure Monitoring Device CFR 882.1620 (84GWM)

2.3 Ventricular Catheter Name

Trade name	Ventricular Catheter
Common name	Ventricular Catheter
Classification name	Ventricular Catheter CFR 882.4100 (84HCA

2.4 Equivalent device

The bolt system is substantially equivalent to ACT II MP plus covered in 510-K 013005. The 005 device is a bolt that can receive the ventricular catheter of ACT III (705) and hold a second parameter probe.

The pressure sensing system used is the same as that used in ACT III. It is covered in 510-K 013705 (705).

The drainage catheter system is similar to that used in 705 except the catheter size is smaller.

The MPS- OXIPORT bolt guide tubes are similar to that described in ACT II MP (005). The guide tubes are substantially equivalent to guide tubes described in Licox (002765) as regards having the tubes extend beyond the dura .

2.5 Description of the Catheter's ICP Monitoring capability

The pressure sensing system elements are identical to that used in ACT III (705). An air tube is placed in the second lumen of a two-lumen ventricular catheter and bonded to the distal end of the lumen. A flaccid bladder affixed to the distal end of the catheter is folded over the side of catheter and attached to the catheter wall. The proximal end of the air tube exits the catheter near its proximal end and is terminated in a piston. The bladder is activated when the piston is inserted into the cylinder of a transducer housing. The bladder and tube convey changes in ICP to a transducer in the transducer housing. The ICP reading is displayed on a patient monitor.

2.6 Description of the ventricular catheter

Other than being of smaller diameter, the catheter is the same as the ACT III catheter (705). A bolt is screwed into the drill hole. The ventricular catheter is then inserted into a ventricle. A slidable insert placed near the proximal end of the catheter is moved into the bore of the bolt. The insert has a fixation feature that anchors the insert to the bolt and a compression fitting to hold the catheter in place.

2.7 Description of the probe guides

Two polyimide probe guides are incorporated into the bolt insert. The probe guides direct the path of probe inserted into the brain. Oxygen probes must be placed in undisturbed tissue. The guide tubes have a deflector which cause a probe to enter the brain at an angle to the bolt axis and thereby move to undisturbed tissue. The distal end of the guide tubes extend to a point just below the dura. The proximal end of each guide tube has a polyurethane pigtail with a luer fitting that provides a means of joining the probe to the pigtail

2.8 Intended Use of the Device

The device is to be used in patients who require continuous ICP monitoring, who may require drainage of CSF and who may require monitoring of other parameters such as tissue oxygen.

2.9 Device Characteristics vs. Predicate Device

Column 2 in table 1 identifies whether the comparison is to ACT II (005) or ACT III (705). The guide tube length predicate is based on the Licox oxygen monitoring system, 765.

Table 1

Characteristic		Predicate Device	MPS- OXIPORT	Comment
Bolt diameter	II	.250"	.250	
Bolt material	II	Polycarbonate	Titanium	
Skull Attachment	II	Ribs	Screw thread	
Catheter OD	III	3.3 mm	2.25 mm	
Sensor length	II	9 mm	37 mm	Bladder volume unchanged. The diameter decreased and length increased.
Pressure catheter bladder	III	Butyl	Butyl	
Depth of bladder in brain	III	6-8 cm	6-8 cm	
Probe guide diameter		1.3 mm	1.3 mm	Ref Licox765
Probe guide length	II	Ti guide tubes extends from top of cap to distal end of bolt	Polyimide guide tubes extend 3 mm beyond the distal end of bolt	Licox guide tubes extend beyond the dura
Ventricular Catheter Length	II	9 "	9"	
Ventricular Catheter OD	III	10 Fr	7.5 mm	

Drainage lumen ID	III	1.8 mm^2	1.6 mm^2	
Catheter material	III	Tecoflex	Tecoflex	
Depth of catheter in brain	II/I	6-8 cm	6-8 cm	
Compatible probe diameter	II	0.7 to 0.9 mm	0.7 to 0.9 mm	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Donald E. Bobo
InnerSpace, Inc.
2933 South Pullman Street, Suite A
Santa Ana, California 92705

Re: K041838
Trade/Device Name: MPS
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: February 3, 2005
Received: February 14, 2005

Dear Mr. Bobo:

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/industry/support/index.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

51Q(k) Number (if known): K041838

Device Name: MPS MPS-T

Indications For Use:

The use of MPS (or MPS-T) by a qualified neurosurgeon is indicated when direct measurement of intracranial pressure is clinically important, when the patient may require CSF drainage in the course of their care and when data from a second or third parameter may be deemed useful in optimum patient management.

Miriam C. Provost

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

510(k) Number K041838

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)