

K072379

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Submitted by:

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APR 29 2008

Contact person: Don Bobo (dbobo@innerspacemedical.com)

Approved 510K Device Name: MPS Oxi-port and MPS Oxi-port-T (T= temperature)

New Device Names:

MPS Hummingbird - (CP)¹ XX² Fr. (Manifold accepts an oxygen probe.)
MPS Hummingbird Plus - (CP) XX Fr. (Manifold accepts both an oxygen probe and a flow or dialysis probe)

1 The letters CP will be added to the name of models that offer Continuous Pressure measurement while draining.
2 XX is a placeholder for the specific Fr sizes offered.

Devices that are MRI compatible will have the words "MRI Conditional" under the device name

Predicate Devices

Predicate device related to Function and Design:

K041838 - Concurrence date 03/01/2005 - Product code GWM: Device, Monitoring, Intracranial Pressure. The catheter uses an air column and bladder to couple ICP to an external transducer. It provides two probe ports.

Predicate device related to temperature sensing in a ventricular catheter

K962928 - Camino. K041838 -InnerSpace.

Predicate device related to the larger size of catheters used in trauma patients:

Camino, Codman and others have a number of pre-amendment ventricular catheters with an OD ranging from 7.5 to 11.5 Fr.

Predicate device related to sensing pressure in parenchyma tissue

K003905 -InnerSpace

Modified Device

1 **CSF drainage** . An 8, 9 and 10 Fr. model will be added to the line. The user will select a Fr. size appropriate for the expected level of debris or clots in the CSF. The following table compares the cross section area of the drainage lumen of MPS catheters to several Camino ventricular catheters now on the market. The catheter body is made of polyurethane rather than silicone. A polyurethane catheter is stronger than silicone and can therefore be extruded with a thinner wall. The drainage lumen of a multi-lumen urethane catheter is therefore as large or larger than a single lumen silicone catheter as can be seen in the following table. The MPS catheter has three lumens, a drainage lumen, a thermocouple lumen and an air column lumen.

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Device names	Fr	OD	Drainage Lumen Sq. in. 10 ⁻³
<i>MPS</i>	8.1	0.106	3.46
Camino Large 2	8.1	0.106	1.96
<i>MPS</i>	9.0	0.117	4.91
Camino Large 1	9.2	0.120	2.37

2 Continuous Pressure An MPS catheter has a thin-wall tube termed the cage attached to its distal end. The cage holds the pressure-sensing bladder and provides the inlet holes through which CSF enters the catheter. If the inlet holes become partially clogged, the pressure drop across the holes can create a lower pressure in the cage than the pressure in the brain. In order to get a true ICP reading, the staff must momentarily stop CSF drainage to eliminate the pressure drop. The Continuous Pressure model eliminates the affect of clogged inlet holes on the ICP reading by inserting a partition into the cage that separates cage into two compartments, an upper compartment for the sensing bladder and a lower compartment for CSF inflow. A transfer tube passing through the bladder compartment conveys CSF from the inflow compartment to the drainage lumen of the catheter. The bladder, now isolated from pressure in the lower compartment, is not affected by pressure changes in the inlet hole compartment due to clogged inlet holes. The addition of a transfer tube to the cage requires an increase in the overall catheter diameter by 1/2 to 1 Fr. depending on the catheter Fr. size.

3 Manifold modification. The manifold of the approved device has two probe ports. The diameter of one of the ports has been increased to allow the passage of either a flow or dialysis probe. Both probes are slightly larger than anticipated in the original manifold design. One probe has been enlarged to accommodate the larger probe. The distal body of the manifold has been extended 1 cm to both accommodate the diameter change and improve the distal end profile for insertion into the brain.

Port diameters	Port 1	Port 2
Approved device	.056"	.056"
Modified device	.056"	.063"

4 MRI The dash T (-T = temperature) catheters of the approved device have an integrated temperature sensor that will be heated by an RF field. The thermocouple of the MRI Conditional catheters has been placed in a removable probe. The probe is removed prior to an MRI and replaced after. The temperature probe is placed in a polyimide tube that has been inserted into a dedicated lumen in the catheter. Both the tube and lumen ends are closed. The temperature probe can therefore be inserted and removed as often as need be as there is no body or fluid contact and therefore no sterility issue. Absent the thermocouple probe, the catheter and the manifold are plastic and therefore MRI safe. The bolt of the Hummingbird HUMV-500MR was subjected radio frequency induced heating. The bolt was found to be "MR Conditional" as defined by ASTM F2503, Standard Practice for Marketing Medical Devices and Other Items for Safety in the Magnetic Resonance Environment using a 1.5 and 3.0 Tesla MR system.

5 Indications for Use

The use of a Hummingbird HUMV-500 or HUMV-500MR 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, when data from one or more parameters may be deemed useful in providing optimum patient management and, in the case of the Hummingbird-500MR, when an MRI may be indicated.



Food and Drug Administration
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Rockville MD 20850

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% Mr. Don Bobo
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APR 29 2008

Re: K072379

Trade/Device Name: Hummingbird HUMV-500MR
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: April 25, 2008
Received: April 25, 2008

Dear Mr. Bono:

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.

Page 2 – Mr. Don Bobo

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

510(k) Number (if known): K072379

Device Name: Hummingbird HUMV-500 and 500 MR

Indications For Use

The use of a Hummingbird HUMV-500 or HUMV-500MR 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, when data from one or more parameters may be deemed useful in providing optimum patient management and, in the case of the Hummingbird-500MR, when an MRI may be indicated.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Neil R. O'Connell for review
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072379