SEP 9 2002

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K013705

Section 2.0 510(k) Summary

2.1 Submitted by

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Contact Donald E. Bobo, ext 12
Prepared Nov.5, 2001

2.2 Device Name

Trade name ACT III Ventricular Catheter

2.2.1 Pressure Monitoring Function

Common name Intracranial Pressure Monitoring Device
Classification name Intracranial Pressure Monitoring Device 882.1620

2.2.2 Drainage Catheter Function

Common name Ventricular Drainage Catheter
Classification name Ventricular Catheter 882.4100

2.3 Equivalent device

The equivalent device to the ACT III Ventricular Catheter is the Camino VENTRIX® True Tech Ventricular Tunneling Pressure Monitoring Kit NL960-V.

2.4 Description of Device

The ACT III Ventricular Catheter consists of a 10 Fr. ventricular catheter in combination with an external pressure transducer. The catheter has two lumens. One lumen drains CSF. The second lumen transmits ICP from the brain to the external transducer by means of an air tube within the lumen. The air tube communicates with a flaccid bladder on the distal end of the catheter. The bladder's volume and internal pressure change according to $P_1V_1 = P_2V_2$. The catheter's proximal end terminates in a piston with an o-ring. The piston is joined to an external transducer. The pressure seen by the bladder/catheter/transducer mirrors the pressure in the brain.

The CSF drainage function is provided by a dedicated lumen within the catheter. The CSF drainage function is typical of ventricular catheters. The length of the catheter fenestrated with radial holes is the same length as that provided by a conventional drainage catheter. The active drainage length of the catheter is preserved by mounting the bladder on the side of the catheter on a segment not penetrated by radial holes.

The technique used to place a ventricular catheter is the same as that used to place a conventional ventricular catheter. Once the distal end of the catheter is placed in the brain, the proximal end of the catheter is placed in the sheath of a trocar and tunneled beneath the scalp in a forward direction. The proximal end of the catheter is bifurcated in order to separate the air lumen and drainage lumen.

It is desirable to keep the size of the proximal end of the catheter small and thereby minimize the diameter of the trocar sheath passed beneath the scalp.

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The size of the proximal end of the catheter has been minimized by the use of a tube-within-a-lumen design. In this design, a dedicated air tube is inserted into a lumen which, to distinguish it from the drainage lumen, will be referred to hereafter as the second lumen. The air tube is bonded to the distal end of the second lumen. The tube then exits the sidewall of the second lumen near the proximal end of the catheter. This construction allows the air tube to separate from the main catheter without the use of a molded bifurcation. As will be seen in the drawings, the concept provides a proximal configuration much smaller than a conventional molded bifurcation.

Once tunneled beneath the scalp, the air tube is pneumatically connected the transducer. The transducer is mounted within a special transducer housing that features a cylinder designed to engage the catheter's piston. The bladder is activated when the piston on the end of the air tube is placed in the cylinder. Connecting the piston to the cylinder causes the air in the cylinder to be injected into the bladder. The bladder air is restored once per shift by removing and replacing the transducer housing. The transducer is incorporated into to a standard patient monitoring cable. The cable can be connected to a patient monitor without the need for a special intermediate instrument.

2.5 Intended Use of the Device

The use of the ACT III Ventricular Catheter by a qualified neurosurgeon is indicated when direct measurement of the intracranial pressure is clinically important and when the patient may require CSF drainage in the course of care.

2.6 Device Characteristics vs. Predicate Device

The essential characteristics of the ISM device vs. the predicate device are shown in the following table.

Characteristic	ACT III Ventricular Catheter	Predicate Device
Tunneling direction	Forward (Traditional)	Reverse
Catheter diameter	10 Fr.	10 Fr.
Drainage lumen diameter	1.5 mm (typical of conventional ventricular catheters)	Not stated
Catheter material	Urethane	Silicone
Electrical interface	Direct connection to patient monitor.	Electro-optical converter connected to patient monitor
Trouble shooting.	Transducer of ACT III can be removed at any time to rezero monitor or replace sensor.	Predicate sensor is part of the catheter and is not removable.
Calibration	Zero transducer at patient monitor	Calibration of instrument required

2.7 Animal and Laboratory testing:

- Test of the device vs. a ventricular catheter in a pig shows the device faithfully follows the ventricular value and waveform.
- Pressure monitoring system was tested according to AAMI requirements as modified for an air column device. The system passed all testing requirements.

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2.8 Conclusion

The **ACT III** Ventricular Catheter, in combination with the ISM –3000 series cable, is equivalent to the predicate device because:

It has the same intended use, namely to sense intracranial pressure and drain CSF.

The system performance complies with AMMI standards for intracranial pressure monitoring, modified to reflect the characteristics of the technology used.

It uses materials that have been shown to be biocompatible and function well in the intended application.

Laboratory testing and basic design assure that no parts will come loose and be left in the patient.

The components are biocompatible and the catheter is a typical 10 Fr. size.

The system is easy to use and does not require the use or calibration of an interface instrument between the system and a patient monitor.

Unlike any other self-referencing in vivo ICP monitor now on the market, the calibration of the transducer can be checked at anytime.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 2002

Innerspace, Inc.
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President
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Santa Ana, California 92705

Re: K013705
Trade/Device Name: ACT III Ventricular Catheter
Regulation Number: 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: Class II
Product Code: GWM
Dated: June 7, 2002
Received: June 11, 2002

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 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,

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 K013705

Device Name **ACT III Ventricular Catheter**

Indications For Use Indications The use of a ACT III Ventricular Catheter by a qualified neurosurgeon is indicated when direct measurement of the intracranial pressure is clinically important and when the patient may require CSF drainage in the course of care.

Please do not write below this line

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The Counter Use ____
(Per 21 CFR 801.109)

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

510(k) Number K013705