SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Submitted by:
InnerSpace
1622 Edinger Ave. Suite C, Tustin CA 92780
Ph 714 259 7900
Fax 714 259 7999

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

Approved 510K Device Name:
MPS Oxiport and MPS Oxiport Plus

New Device Names:
Trilogy

Predicate Device
Predicate device: K072379 MPS Oxiport Plus.

Summary
This submittal covers a device that allows the placement of a ventricular catheter and up to three probes through one bolt. The pressure sensor is an air-based system that has a deformable chamber. The pressure in the chamber mirrors ICP. It is transmitted to an external transducer. The submittal also includes several procedure accessories, a device that sets the proper length of a probe to be inserted into the Trilogy, a tripod that indicates the correct drill angle, a series of tubes that fit on the shank of the bolt that cause the distal end of the bolt to stop when it reaches the inner table, an improved drill bit stop and an improved pump that injects air into the catheter's sensing system.

Device modifications

Three probe capability
The present design provides the ability to guide 2 probes into the brain. A 3rd probe capability has been added to the manifold through which probes pass en route to the brain. The manifold is a component that snaps into a well in the bolt. The pigtails through which the probe will pass are bonded to the top of the body of the manifold. The probe guidance features extend from the distal face of the manifold body. The guidance system provides two functions, that of guiding the probe to the brain and that of changing the probe's trajectory to direct it away from tissue disturbed by the ventricular catheter. The present manifold incorporates both functions in a single injection-molded part. A straight section guides the catheter to the brain and a curved segment molded into the distal end of the guide tube changes the trajectory of the probe. The modified manifold, in contrast, uses a separate part for each function. A thin-wall tube guides the probe to the brain. A second tube is used to change the trajectory of the probe. The guide tube is bonded to the

distal side of the main body of the manifold. It enters the brain when the manifold is placed in the bolt. Once the guide tube is in place, the 2nd tube is inserted through the guide tube. As it exits the guide tube, it forms a curved shape that will define the trajectory of the probe as it passes through the curve. The second tube in essence acts as an introducer for a probe that is to be inserted into the brain. The exact trajectory of a probe is defined by a key and keyway design. The introducer has a small axial ridge that acts as a key. The body of the manifold has a keyway. The user must align the key and keyway to advance the introducer through the guide tube. The orientation of the keyway thereby defines the exit direction of the introducer. The design is particularly compact. The brain volume displaced by the 3-probe manifold design that uses two thin-wall tubes is the same as that of the 2-probe injection molded design used in the present device. The bolt diameter is enlarged 10% to provide the space required to accommodate a third pigtail on top of the body of the manifold.

Pressure Sensor

This modification involves moving the sensor high enough on the catheter that it does not enter the ventricle. Moving the sensor into parenchymal tissue addresses a problem common to all ventricular catheters. If CSF is over drained, the ventricular wall will collapse around the catheter. Should this happen, CSF cannot be drained nor pressure read. This modification solves the slit ventricle problem by placing the sensor high enough on the catheter that it never gets into the ventricle. The ability of the sensor to work in parenchymal tissue is described in K003905.

The sensor uses the same dip-molded bladder as used in the present MPS. The end of the bladder is cut off thereby forming an opened ended tube. The sensor is manufactured by bonding a ring on the catheter on either side of a hole leading to the air lumen. The bladder is placed over the rings and then bonded to them. The principle of operation is unchanged, i.e., it is a variable volume sensor based on Boyle's Law.

Evolutionary Modifications Entered For The Record

The system has evolved in minor ways since the approved K072379. They are entered for the record.

Air Injection System

The pressure sensor consists of a partially filled bladder that transmits pressure via an airline to an external transducer. The bladder needs to be recharged once per shift to compensate for air lost by diffusion. As described in the prior submission and IFU, the sensor is unable to read pressure if it is recharged when ICP is < 3 mm Hg. When the bladder is exposed to the atmosphere, it is collapsed by the ICP. If the ICP is not high enough to completely collapse the bladder, the residual air volume, when combined with the injected air volume, over inflates the bladder. Even though the staff knows the ICP is low, the present air injection system is frustrating in that an exact ICP value is not available and that the monitor reading is always wrong. The modified air injection system provides a correct ICP reading regardless of the ICP at

the time air is injected into the bladder. It does so by removing residual air before injecting air. The starting air charge is therefore always the same.

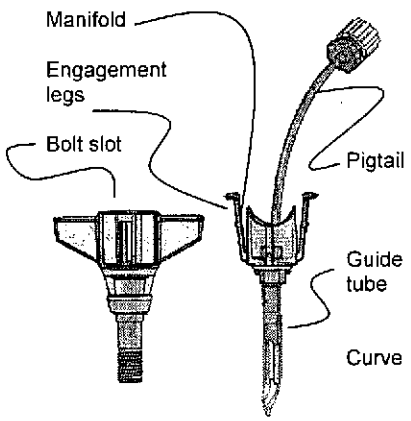
Drill angle - A correctly angled burr hole will minimize the number of catheter insertions required to hit a ventricle. A tripod helps the surgeon set the correct angle between the skull and drill bit before drilling the burr hole. The tripod is removed after the correct drill angle is seen and before the drilling process begins.

Drill Stop
The function of a drill stop is to prevent the drill bit from plunging into the brain as it suddenly breaks through the inner table of the skull. The hassle of setting and resetting the drill stop is such that is not uncommon for the surgeon to remove the drill stop before drilling and lose the benefit of the protection afforded by the stop. The modified drill stop avoids the set-and-reset hassle and thereby increases the likelihood that the surgeon will use a drill stop. The stop is a two-piece assembly that has an integrated spacer. The stop's setscrew is tightened at such time as the bit breaks through the inner table. The break-through event is unmistakable as the bit hangs up on the hole edge and prevents the bit from rotating. At this time, the drill is reversed to release it. The spacer is then removed. The bit can now be advanced a distance equal to the thickness of the spacer. The design takes the guesswork out of setting a stop in a position that will allow the drill bit to go through the skull but stop as soon as it clears the skull.

Bolt Stop – The bolt used in all of the Hummingbird systems must be screwed in until it is near the bottom of the burr hole. The skull thickness is shown on the drill bit. The bolt advances 1 mm per turn. The surgeon therefore must count the turns required to properly position the bolt. The bolt stop relives the surgeon from keeping track of the turns. A selection of defined length tubes are provide in the tray. The surgeon selects the tube that matches the skull thickness. The tube is placed on the threaded portion of the bolt. A feature in the bolt stops the tube once it is moved all the way on the threaded shaft. The stop eliminates the need for the surgeon to count rotations to move the bolt to the inner table and assures that the bolt will indeed be moved to the proper depth.

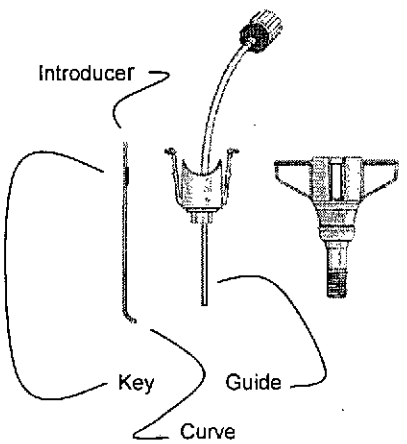
Drawings
There are two sets of drawings. The first set of drawings describes the system modifications for which permission to market is sought. The second set of drawings describes evolutionary changes that have occurred.

Set 1 - System Modifications

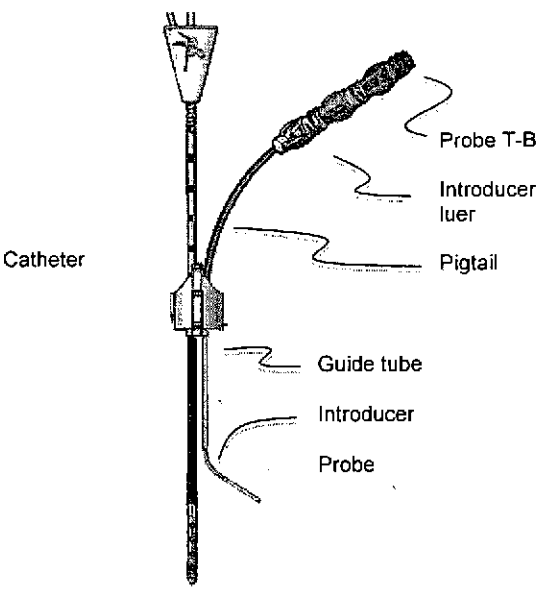


Present Manifold Both the present and modified manifolds are fixed to the bolt by the engagement leg on the side of the manifold. The leg snaps into a slot in the front of the bolt. The bolt has been rotated 90 degrees to show the slot. Probe pigtails are bonded in a well on the top of the manifold. Only one pigtail is shown for the sake of clarity. A guide tube, shown in partial cross section, guides the probe into the brain. The exit trajectory of a probe is set by the curve shown in the distal end.

Modified Manifold Two thin-wall tubes have replaced the single piece injection molded part. The first tube is a guide tube (middle dwg). It extends from the manifold to the brain. Only one tube is shown for clarity.



The second tube (far left) acts as an introducer. The drawing shows the lower end of the introducer. The ridge at the top is the key that must be lined up with a keyway in the main body of the manifold. The introducer is passed through the first tube. The curve formed in its distal end straightens as it passes through the guide tube and reforms as it exits the guide tube. The probe is passed through the introducer. The direction the probe exits the bolt is determined by the orientation of the keyway.



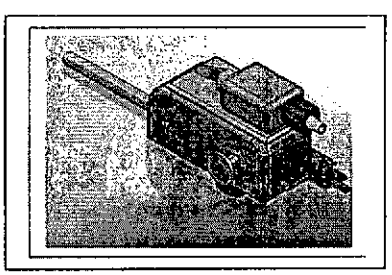
This drawing shows the catheter, guide tube, introducer and probe when the probe placement procedure is completed. The thin wall guide tubes are more space efficient than an injection molded part. The footprint of the 3-probe design of the modified device is therefore similar to that of the current 2-probe design. The modified manifold requires a 10% larger diameter bolt to make room for the 3rd pigtail on the top face of the manifold.

Measuring tube Probes must sometimes be moved several mm at times in order to find a suitable monitoring site. The probes are therefore fixed to the introducer by a T-B fitting. A measuring tube sets the length of the probe that will enter the brain. The measuring tube is a polyurethane tube that has been pushed on the distal end of the T-B. The probe is passed through the T-B until it reaches the end of the measuring tube. The T-B is the tightened. The TB with probe attached is pulled from the tube and inserted into the introducer. A drawing of the tube is presented in Set 2 of the drawings.

The placement procedure once the bolt is in place is as follows. A catheter is passed through the bolt and placed in a ventricle. The manifold is then moved down the catheter and snapped to the bolt. The guide tubes of the manifold pass 2 mm below the dura. When the surgeon elects to place a probe, an introducer is placed through the guide tube and its luer joined to the luer of the pigtail that leads to the guide tube. Next, the probe is passed through the introducer. The T-B luer is connected to the luer of the introducer and tightened.

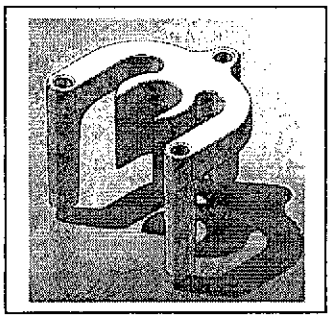
Drawings – Set 2 Evolutionary changes

The following drawings describe several evolutionary changes in the system since the original 510 (k) submission and are set forth as a matter of record



Air Management System The air in the sensor is recharged once per shift to replace air lost by diffusion. The amount of air remaining in the sensor at the time the sensor is open to air varies with the extent to which the ICP has collapsed it. If ICP is < 3 mm Hg at the time the sensor is recharged with air, the high residual air volume in the sensor, when added to the injected air, over pressurizes the sensor. This interferes with the system's ability of the system to read pressure low pressure. The Air Management System (AMS) eliminates the problem. The device consists of a set of pistons and cylinders. The movement of the pistons in one direction removes residual air from the system so the starting volume of air in the system is always the same regardless of ICP. The continuing movement of the piston injects a defined volume of air. The sensor thereby always is recharged with the same amount of air.

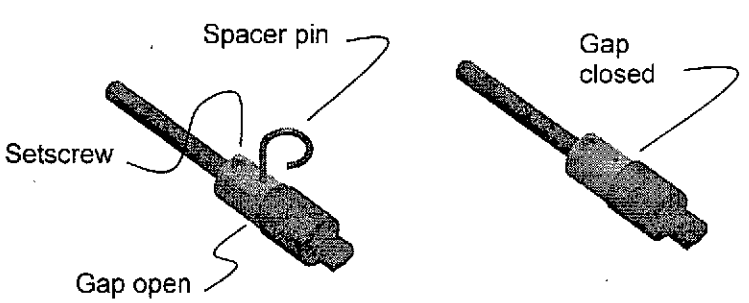
The AMS also has a shut-off valve. It isolates the sensor from the piston set. The gasket on the valve is more easily accessed than the o-rings on the piston set, so biomedical engineering can replace it annually, thereby assuring that the operation of the system will not degrade with time due to wear of the seals.



Drill bit alignment If the angle of the drill bit to the skull is incorrect at the time the burr hole is drilled, it is difficult or impossible for a catheter to be inserted into a ventricle even after multiple attempts. Neurodynamics has several 510K approved devices that are based on the fact that a line perpendicular to an imaginary plane defined by the legs of a tripod on the skull passes through the ventricle. The Neurodynamics system physically controls the path of the drill as the burr hole is made. Though technically sound, the devices have found limited acceptance due to the complexity they add to the procedure. A tripod has been added to the system that helps the surgeon visualize the correct drill angle between the bit and the skull. It is removed before drilling begins. It does not control the drill angle during the drill process. It just shows the proper drill angle. The tripod will be of particular interest to residents.

The drill stop is placed in the cylinder at the center of the tripod. The tripod is then placed on the scalp. The surgeon sees the correct drill angle at this time. The tripod is lifted up and moved away from the drill stop. The burr hole is then drilled.

Bolt stop The device, Trilogy, requires that the distal end of the bolt be placed within a couple of mm of the inner table of the skull. The drill bit has mm marks that allow the surgeon to read the thickness of the skull. The bolt moves into the burr hole 1 mm per turn. The bolt is properly position when the bolt is turned a number of rotations equal to the thickness of the skull. At present, the surgeon needs to keep count of the number of bolt turns. The bolt stop does away with the need to count. The stop is a tube that goes over the threaded shank of the bolt. The surgeon selects a tube length equal to or one mm less than the skull thickness read and places it on the distal end of the bolt. The surgeon then screws the bolt into the burr hole until the stop hits the skull. Various combinations of the tubes provide stops for a skull thickness between 4 and 20 mm.



Drill stop
The drill stop has a lower part that can slide an upper part that holds the setscrew. The two parts are held apart by a spacer pin. As the drill bit enters the inner table, it hangs up. The stop is moved to the skull and the setscrew tightened. The spacer pin is removed. The bit can now advance a distance equal to the diameter of the pin. The advance will allow the bit to pass through the skull but not beyond.

Probe length The system is designed to place probes made by other manufacturers into the brain. A measuring tube is provided to set the length a probe enters the brain so the distal tip is always properly located. A plastic tube is placed on the end of a T-B. The probe is passed through the tube until it reaches the end of the measuring tube. The T-B is then tightened, removed from the measuring tube and inserted into the introducer. A short length or polyimide tube is placed in the proximal end of the T-B. It provides additional support to the probe as it enters the curve. The support makes the probe placement smooth through out the placement process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

InnerSpace
% Mr. Don Bobo
1622 Edinger Avenue, Suite C
Tustin, Califoornia 92780

SEP 2 9 2009

Re: K083378
Trade/Device Name: Trilogy
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: July 24, 2009
Received: July 28, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): Not assigned K083378

Device Name: Trilogy

Indications For Use:

The use of a Trilogy system 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 one or more parameters may be deemed useful in providing optimum patient management.

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)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083378