OCT 2 2 2004

510(k) Summary

K042728

September 29th 2004

1 Submitter

Novus Monitoring Ltd
Greenways
Abbotts Ann, Andover
Hampshire, SP11 7BH
United Kingdom

Contact Person: Prof. Peter F Gibson
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2 Name of Device

Proprietary Name: Camino Slim-Line™ Intracranial Pressure Monitoring System, comprising:

a) Camino Slim-Line™ monitor
b) Camino Slim-Line™ parenchymal and sub-dural ICP catheter

Common Name:

a) Intracranial Pressure monitor
b) Parenchymal and sub-dural catheter for intracranial pressure measurement

Device Classification: Intracranial pressure monitoring devices have been placed in Class II as per 21 CFR Regulation Number 882.1620 and assigned the Product Code GWM.

3 Predicate Devices

The components of the Camino Slim-Line™ system are substantially equivalent to the following legally marketed devices:

K013930	NeuroSensor™ System
K914479	Codman ICP monitoring system and Microsensor™ ICP transducer
K853864	Camino Intracranial Pressure Monitoring Kit

This statement is based on the subject device's similarity to the predicate devices in intended use, materials, design and principles of operation.

4 Device Description

The Camino Slim-Line™ system consists of a single-use 1.3mm diameter parenchymal and sub-dural catheter for the real-time measurement of intracranial pressure (ICP) and an in-line cable monitor for the display of measured pressure. The Camino Slim-Line™ monitor can be connected to an external patient monitoring system to relay ICP measurements.

ICP is monitored directly by a solid state sensor mounted on the side of the Camino Slim-Line™ ICP catheter close to its tip. The sensor is precalibrated in the factory with probe identification and calibration values stored within each probe and there is no requirement for the user to calibrate the probe before use.

The Camino Slim-Line™ monitor uses a small LCD display to show the measured ICP continuously in real time, both in digital form and as a real-time trace. The monitor can relay this measured information to an external patient monitoring system.

In parenchymal applications, the Camino Slim-Line™ ICP catheter is used with an existing single-use Camino cranial access port or bolt, and an existing Camino convenience procedure kit for cranial access. For Sub-dural applications the Camino Slim-Line™ ICP catheter may be used with an existing tunneling trocar and convenience procedure kit for cranial access.

5 Intended Use

The Camino Slim-Line™ system has been designed for use by a qualified neurosurgeon in the direct monitoring of intracranial pressure in both sub-dural and intraparenchymal applications.

6 Summary of Substantial Equivalence

The Camino Slim-Line™ Intracranial Monitoring System is similar in design, construction, materials, intended use and performance characteristics to the predicate devices. In vitro testing shows that the device meets similar performance specifications as those for the predicate devices. No new issues of safety or effectiveness are introduced by using this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2004

Novus Monitoring Ltd
c/o Ms. Judith E. O'Grady
Senior Vice President, Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K042728
Trade/Device Name: Camino Slim-Line™ Intracranial Pressure Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: September 30, 2004
Received: October 1, 2004

Dear Ms. O'Grady:

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/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

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

510(k) Number (if Known): K042728

Device Name: Camino Slim-Line™ Intracranial Pressure Monitoring System

Indications for Use: The Camino Slim-Line™ Intracranial Monitoring System has been designed for use by a qualified neurosurgeon in the direct monitoring of intracranial pressure in both sub-dural and intraparenchymal applications.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Miriam C Provost

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

510(k) Number K042728