FEB 2 0 2002

510(k) Summary

November 26th 2001

k013930 1/3

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: NeuroSensor™ system, comprising:

a) NeuroSensor™ monitor
b) NeuroSensor™ parenchymal probe
c) NeuroSensor™ cranial access port
d) NeuroSensor™ cranial access procedure kit

Common Name:

a) Cerebral Blood Flow and Intracranial Pressure monitor
b) Parenchymal probe for cerebral blood flow and intracranial pressure measurement
c) Intracranial bolt
d) Convenience procedure kit for cranial access

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.

Extravascular blood flow probes and blood flowmeters have been placed in Class II as per 21 CFR Regulation Number 870.2120 (Product Code DPT) and 21 CFR 870.2100 (Product Code DPW), respectively.

3 Predicate Devices

The components of the NeuroSensor™ system are substantially equivalent to the following legally marketed devices:

K914479	Codman ICP monitoring system and Microsensor™ ICP transducer
K896515	Vasamedics Model BPM2 Laser Doppler Perfusion Monitor

K961368	Vasamedics Trimflo™ parenchymal blood flow monitoring kit
K974088	Codman Intracranial Bolt

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 NeuroSensor™ system consists of a single-use combined 2mm diameter parenchymal probe for the real-time measurement of cerebral blood flow (CBF) and intracranial pressure (ICP) and a monitor for the display and storage of these measured variables and the computation and display of derived variables.

CBF is measured using Laser Doppler flowmetry and provides real-time measurements of local blood flow in the brain. In the NeuroSensor™ system, low power laser light at 780nm is transmitted down a central fiber to the tip of the probe and illuminates the cerebral tissue. The laser light is scattered by the moving red blood cells and is collected by an array of collecting fibers at the tip of the probe. The reflected light is measured and the resulting signal processed to produce a measure of the perfusion or flux of blood in the local tissue sample volume. The flow measurement is converted into absolute units of ml/min/100g using an algorithm determined by a comparison between measurements made using the combined Laser Doppler probe and the reference method of Quantitative Autoradiography.

ICP is monitored directly by a solid state sensor mounted on the side of the NeuroSensor™ probe 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 NeuroSensor™ monitor uses a color LCD display to show the two measured variables CBF and ICP continuously in real time, both in digital form and as a real-time trace. The monitor can accept measured arterial pressure from an external patient monitor, and can use this data and the measured CBF and ICP to derive cerebral perfusion pressure (CPP) and cerebrovascular resistance (CVR). Data is stored by the monitor and can be displayed as a trend graph over a period of 15 minutes, or 1,2,8 or 24 hours.

Completing the system is a single-use cranial access port featuring a titanium alloy bolt, and a convenience procedure kit for cranial access.

5 Intended Use

The NeuroSensor™ system has been designed for use by a qualified neurosurgeon in monitoring cerebral blood flow in patients at risk of cerebral ischemia, and for the direct monitoring of intracranial pressure in both sub-dural and intraparenchymal applications.

6 Summary of Substantial Equivalence

The NeuroSensor™ system is similar in design, construction, materials, intended use and performance characteristics to the predicate devices. It differs in combining the measurement of CBF and ICP into a single combined probe. 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

Mr. Peter F. Gibson
Managing Director
Novus Monitoring Ltd.
Greenways
Abbotts Ann, Andover
Hampshire, SP11 7BH
United Kingdom

FEB 2 0 2002

Re: K013930
Trade/Device Name: NeuroSensor™ System
Regulation Number: 870.2120, 882.1620
Regulation Name: Extravascular blood flow probe
Intracranial pressure monitoring device
Regulatory Class: II
Product Code: DPW, GWM
Dated: November 26, 2001
Received: November 28, 2001

Dear Mr. Gibson:

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" (21CFR 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,

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 Statement

Ver/ 3 - 4/24/96

Applicant: Novus Monitoring Ltd

510(k) Number (if known): K013930

Device Name: NeuroSensor™ System

Indications For Use:

The NeuroSensor™ System is intended for use by a qualified neurosurgeon in monitoring cerebral blood flow in patients at risk of cerebral ischemia, and for the direct monitoring of intracranial pressure in both sub-dural and intraparenchymal applications.

Miriam C. Provost

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

510(k) Number K013930

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)