510(k) SUMMARY

Submitter's name and address:

Integra NeuroSciences
5955 Pacific Center Blvd.
San Diego, CA 92121, USA

Contact person and telephone number:

Nancy A. Mathewson, Esq.
Director, Regulatory Affairs
(858) 455-1115 ext. 185

Date summary was prepared:

March 18, 2005

Name of the device:

Proprietary Name:	
Modified:	NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System
Unmodified	NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System, 510(k) K013930
Common Name:	Cerebral Blood Flow and Intracranial Pressure Monitoring System
Classification Name:	Extravascular Blood Probes Product Code DPT, 21 CFR 870.2120 Blood Flowmeters Product Code DPW, 21 CFR 2100
Classification Panel:	Cardiovascular Device Panel
Classification Name:	Intracranial Pressure Monitoring Device Product Code GWM, 21 CFR 882.1620
Classification Panel:	Neurology Device Panel

Substantial Equivalence:

The modified NeuroSensor® System has the following similarities to the unmodified NeuroSensor® System.

Table II – Substantial Equivalence

Parameter	Original NeuroSensor® System	Modified NeuroSensor® System
Indications for Use	Intended for use by a qualified clinician in monitoring cerebral blood flow in patients at risk of cerebral ischemia, and for the direct monitoring of intracranial pressure in intraparenchymal applications.	Identical to the original NeuroSensor® System
Measured parameters	Cerebral Blood Flow and Intracranial Pressure	Identical to the original NeuroSensor® System
Operating Principle	Laser Doppler for measurement of blood flow and MEMS strain gauge pressure sensor for measurement of ICP	Identical to the original NeuroSensor® System
Probe Construction	Type 304 stainless steel or titanium probe	Identical to the original NeuroSensor® System
Probe Body Size	6F (2.0mm) diameter	Identical to the original NeuroSensor® System
Probe Working Length	25mm with 5 depth markings at zero insertion from bolt and at 5mm intervals	Identical to the original NeuroSensor® System
System Specifications (Cerebral Blood Flow)	Range 0 to 300 ml/100g/min Resolution 1ml/100g/min	Identical to the original NeuroSensor® System
CBF Sensor Type	Fiberoptic (Laser Doppler Flowmetry)	Identical to the original NeuroSensor® System
ICP Sensor Type	MEMS (Micro-Electro Mechanical System) silicon strain gauge	Identical to the original NeuroSensor® System
Indwelling time	Five (5) days	Identical to the original NeuroSensor® System
Method of Probe Placement	Inserted through a cranial access bolt	Identical to the original NeuroSensor® System
Packaging Method and Materials	Tyvek lid heat sealed to a thermoformed tray inserted into a second thermoformed tray. Boxed individually.	Identical to the original NeuroSensor® System
Sterilization Process	100% Ethylene Oxide to a sterility assurance level of 10^{-6}.	Identical to the original NeuroSensor® System

Device Description:

Each NeuroSensor® system consists of a single-use probe and introducer for the continuous real-time measurement of Cerebral Blood Flow (CBF) and Intracranial Pressure (ICP), and a monitor for the display and storage of these measured parameters

and the computation and display of derived parameters. The NeuroSensor® monitor can be connected to a hospital bedside monitor for display of ICP. The NeuroSensor® monitor can accept Systemic Arterial Pressure (SAP) data from a hospital bedside monitor, and can use this data and the measured CBF and ICP to compute Cerebral Perfusion Pressure (CPP) and Cerebrovascular Resistance (CVR).

Statement of Intended Use:

The NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System is intended for use by a qualified clinician in monitoring cerebral blood flow in patients at risk of cerebral ischemia, and for the direct monitoring of intracranial pressure in intraparenchymal applications.

Safety:

Biocompatibility studies were conducted per FDA G95-1 and ISO 10993 and have demonstrated that the materials used to manufacture the NeuroSensor® probe are safe for their intended use.

In addition, the NeuroSensor® System was subjected to extensive performance testing. Results of the testing showed that the probe design was technically sound and the product safe for its intended use.

The NeuroSensor® System manufacturing process complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

Conclusion:

In summary, the NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System described in this submission is substantially equivalent to the unmodified predicate device and the modifications made do not affect the intended use or fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2005

Integra Neurosciences Corporation
Ms. Nancy Mathewson
Integra Lifesciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K050720
Trade/Device Name: NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: May 4, 2005
Received: May 5, 2005

Dear Ms. Mathewson:

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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting 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): K050720

Device Name: NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System

Indications For Use: The NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System is intended for use by a qualified clinician in monitoring cerebral blood flow in patients at risk of cerebral ischemia, and for the direct monitoring of intracranial pressure in intraparenchymal applications.

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)

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

510(k) Number K050720