APR 2 0 2004

K040235

LICOX PMO Brain Oxygen Monitoring System, 510 (K) SUMMARY

Submitter's name and address:

Integra LifeSciences, dba Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536, USA

Contact person and telephone number:

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

Date summary was prepared:

January 29, 2004

Name of the device:

Proprietary Name:	LICOX PMO Brain Oxygen Monitoring System
Common Name:	Brain Oxygen and temperature monitoring device
Classification Name:	Intracranial Pressure Monitoring Device, 21 CFR 882.1620, 84GWM
Classification Panel:	Neurology Device Panel

Substantial Equivalence:

The features of the LICOX PMO System are substantially equivalent to those of a legally marketed predicate device, the LICOX Brain Oxygen Monitoring System, which was cleared to market under 510(k) K002765 and 510(k) K020558.

Both devices were designed and are manufactured by the same company, GMSmbH, Kiel-Mielkendorf, Germany, which is an Integra LifeSciences/Integra NeuroSciences Company.

Device Description:

The LICOX PMO System consists of a combined oxygen and temperature probe, the PMO Interface Device and cranial access accessories. The following is a list of products covered by this submission, grouped into the following categories: Disposables, PMO Interface Device and associated cables. The list does not

include minor accessories such as cables or convenience kits that are combinations of items listed below.

Table 1
LICOX PMO Brain Oxygen Monitoring System
Model Numbers and Description

	Model Number	Product Description
Disposables	CC1.P1	Combined Oxygen and Temperature Sensing Probe
	IP1	Introducer Kit with Bolt, for use with CC1.P1 Oxygen/Temperature Probe
	IP2	Introducer Kit, two way, for CC1.P1. Oxygen/Temperature Probe and an ICP Probe
	VK5.2	Introducer Kit, trocar/sleeve for tunneled placement of the CC1.P1
PMO Interface Device	PMO.BOX	Patient monitor interface
Monitor Accessories	BC10. PMO	Connects the CC1.P1 to the existing LICOX Monitor, AC3.

Statement of Intended Use:

The LICOX PMO Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. LICOX System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

Comparison of technological characteristics to the predicate device:

	LICOX Brain Oxygen Monitoring System (K002765)	LICOX PMO Brain Oxygen Monitoring System
Indications	The LICOX Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. LICOX System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
Anatomical Site	Brain parenchyma	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
Target Population	Head trauma, craniotomy, with possible hypoxia or ischemia.	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
	LICOX CMP Monitor	**LICOX PMO Interface Device**
Operation	Analog with Microprocessor	Analog only
Screen	Alpha-numeric	None
Monitoring	Continuous	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
Power Supply	Custom A/C-D/C Supply	Powered by battery or excitation voltage of patient bedside monitor
Data output	Serial and Analog	Analog only
Dimensions	34 cm x 32 cm x 8.5 cm	8 cm x 18cm x 4.5 cm
Weight	4.2 kg	2.7 kg
Case material	Plastic	Plastic
Operating Temperature	+10°C to +40°C	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
	LICOX Sensor	**LICOX PMO Sensor**
Parameters	Brain PbtO2 Temperature	Brain PbtO2
Sterility	Sterile	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
Single-use	Yes	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.

	LICOX Brain Oxygen Monitoring System (K002765)	LICOX PMO Brain Oxygen Monitoring System
Single-use	Yes	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
Monitoring duration	5 days	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
Tissue contacting material	Polyethylene	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
O_2 Sensing technology	Clark Cell	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
Outside diameter	0.8 mm	0.65 to 1.3 mm
Patient Access	Introducer and Bolt Kit, tunneling trocar and sheath	Introducer and bolt kit, tunneling trocar and sheath
Calibration	Smart Card calibrated to each oxygen sensor during manufacture, Smart Card read by monitor at time of use	Calibration information stored within the connector and calibrates automatically when connected to the PMO Interface Device. Or Identical to the currently marketed LICOX Brain Oxygen Monitoring System when used with the LICOX CMP monitor.
In Vitro Accuracy, PbtO2	±2.0mmHg (0-20 mm Hg) ±10% (21 mm Hg-50 mm Hg) ±13% > 51 mm Hg	Identical to the currently marketed LICOX Brain Oxygen Monitoring System.
	LICOX Temperature Sensor	**LICO PMO Sensor**
Temperature Sensing Technology	Type K thermocouple as part of the C8.B temperature probe	Type K thermocouple incorporated into the CC1.P1 probe
In Vitro Accuracy, Temperature	±0.2°C	N.A

Safety

Biocompatibility studies were conducted per FDA G95-1 and ISO 10993 and have demonstrated that the materials used to manufacture the LICOX oxygen / temperature sensing probe, probe introducer, bolt and tunneling sheath are safe for their intended use.

In addition, the LICOX PMO Brain Oxygen Monitoring 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 LICOX PMO Brain Oxygen Monitoring System manufacturing process complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

Conclusion:

Management of the neurological recovery of patients who suffer a traumatic brain injury or undergo brain surgery may be aided by the use of monitoring systems such as the LICOX PMO Brain Oxygen Monitoring System. When used in conjunction with the existing armamentarium, direct monitoring of the Partial Pressure of Oxygen in brain provides the clinician with an additional significant parameter that can be used to avoid secondary insult and improve recovery.

The LICOX PMO Brain Oxygen Monitoring System is substantially equivalent to the predicate devices delineated in the submission and the requirements for a Premarket Notification 510(k) as defined in 21 CFR, Part 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2004

Ms. Nancy A. Mathewson, Esq.
Director, Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K040235
Trade/Device Name: LICOX PMO Brain Oxygen Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: January 29, 2004
Received: February 2, 2004

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 (301) 594-4659. 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,

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

510(k) Number (if known): K040235

Device Name: LICOX PMO Brain Oxygen Monitoring System

Indications For Use: The LICOX PMO Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. LICOX System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

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)

Miriam C. Provost

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

510(k) Number K040235