K053244

LICOX® IT2 Complete Brain Tunneling Probe Kit

510(k) SUMMARY

MAY 10 2006

Submitter's name and address:

Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Contact person and telephone number:

Jon Caparotta, RAC
Director, Regulatory Affairs
609-936-2495

Date summary was prepared:

11/10/2005

Name of the device:

Proprietary Name:	LICOX® *IMC* Complete NeuroMonitoring System - LICOX® IT2 Complete Brain Tunneling Probe Kit
Common Name:	Brain Oxygen Monitoring Device
Classification Name:	Intracranial Pressure Monitoring Device, 21 CFR 882.1620, 84GWM
Classification Panel:	Neurology Device Panel

Substantial Equivalence:

The LICOX® IT2 Complete Brain Tunneling Probe Kit components was designed to have the same indications for use and perform to the same specifications as the components used with the LICOX® IT2 Complete Brain Tunneling Probe Kit (510(k) K040235).

Device Description:

The LICOX® IT2 Complete Brain Tunneling Probe Kit is intended for use with the LICOX Brain Oxygen Monitoring System. The LICOX Brain Oxygen Monitoring System measures intracranial oxygen and temperature.

Statement of Intended Use:

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.

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Safety:

No material changes were made to the LICOX® IT2 Complete Brain Tunneling Probe Kit components therefore no new Biocompatibility studies were necessary.

The LICOX® IT2 Complete Brain Tunneling Probe Kit components were subjected to MRI testing, which included Radio Frequency Induced Heating, Magnetically Induced Displacement Force and Torque. Results of the testing showed that the kit components were "MR Conditional" as defined in Draft ASTM F 2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

The LICOX® IT2 Complete Brain Tunneling Probe Kit manufacturing process complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

Conclusion:

The LICOX® IT2 Complete Brain Tunneling Probe Kit is substantially equivalent to the unmodified LICOX® IT2 Complete Brain Tunneling Probe Kit. The labeling revision does not affect the intended use or the 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 10 2006

Integra™
% Mr. Jon Caparotta, RAC
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K053244
Trade/Device Name: LICOX IT2 Complete Brain Tunneling Probe Kit
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: May 7, 2006
Received: May 12, 2006

Dear Mr. Caparotta:

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.

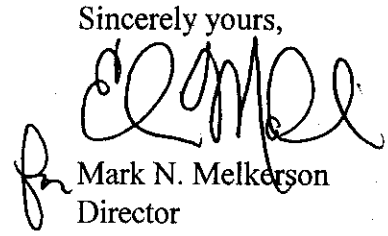
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Mark N. Melkerson
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): K053244

Device Name: LICOX® IT2 Complete Brain Tunneling Probe Kit

Indications For Use:

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.

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

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

510(k) Number K053244