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CONFIDENTIAL

k022253

# Camino® Intracranial Pressure Monitoring Catheter with LICOX® IMC Bolt Fitting

## Model 110-4L

### 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) 622-2737

**Date summary was prepared:**

August 1, 2002

**Name of the device:**

| | |
|---|---|
| Proprietary Name: | Camino® Intracranial Pressure Monitoring Catheter with LICOX® IMC Bolt Fitting, Model 110-4L |
| Common Name: | Intracranial Pressure Monitoring Kit |
| Classification Name: | Intracranial Pressure Monitoring Device Product Code GWM, 21 CFR 882.1620 |
| Classification Panel: | Neurology Device Panel |

**Substantial Equivalence:**

The modified Camino® Intracranial Pressure Monitoring Catheter with LICOX® IMC Bolt Fitting, Model 1104L is substantially equivalent in function and intended use to the original Camino® Intracranial Pressure Monitoring Catheter with LICOX® IMC Bolt Fitting, Model 110-4L.

**Device Description:**

The Camino® 110-4L Catheter is a sterile transducer-tipped pressure monitoring catheter with accessory items to be used as a diagnostic tool for rapidly determining and continually monitoring intracranial pressure. The 110-4L is to be

used in conjunction with LICOX® IM2 or IM3 bolt and Camino® Intracranial Pressure Monitors model MPM-1 or V420 and their associated cables.

**Statement of Intended Use:**

The Camino® Intracranial Pressure for Use Monitoring Catheter with Licox IMC Bolt Fitting, Model 110-4L is indicated for use by a qualified Neurosurgeon when direct measurement of intracranial pressure in the parenchyma or subarachnoid space is clinically important. The Camino® Intracranial Pressure Monitoring Catheter with Licox IMC Bolt fitting, Model 110-4L is intended to be used only through a Licox Brain Oxygen Monitoring System Bolt.

**Safety:**

Biocompatibility studies were conducted per FDA G95-1 and ISO 10993 and have demonstrated that the materials used to manufacture the Camino® 110-4L catheter are safe for its intended use.

In addition, the Camino® 110-4L catheter was subjected to extensive mechanical testing, which included pressure, pull and bend tests. Results of the testing showed that the catheter design was mechanically sound and safe for its intended use.

The Camino® 110-4L catheter manufacturing process complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

**Conclusion:**

The modified Camino® 110-4L catheter is substantially equivalent to the original Camino® 110-4L catheter. The modifications do 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

AUG 2 0 2002

Integra NeuroSciences
Nancy A. Mathewson, Esq.
Director, Regulatory Affairs
5955 Pacific Center Boulevard
San Diego, California 92121

Re: K022553
Trade/Device Name: Camino® Intracranial Pressure Monitoring Catheter with LICOX® IMC Bolt Fitting, Model 110-4L
Regulation Number: 882.1620
Regulation Name: Intracranial Pressure Monitoring Devicce
Regulatory Class: Class II
Product Code: GWM
Dated: August 1, 2002
Received: August 2, 2002

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 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" (21 CFR 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,

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

# APPENDIX B

## Indications for Use Statement

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**510(k) Number** K022553

**Device Name:** Camino® Intracranial Pressure Monitoring Catheter with LICOX® IMC Bolt Fitting, Model 110-4L

**Indications** The Camino® Intracranial Pressure for Use Monitoring Catheter with Licox IMC Bolt Fitting, Model 110-4L is indicated for use by a qualified Neurosurgeon when direct measurement of intracranial pressure in the parenchyma or subarachnoid space is clinically important. The Camino® Intracranial Pressure Monitoring Catheter with Licox IMC Bolt fitting, Model 110-4L is intended to be used only through a Licox Brain Oxygen Monitoring System Bolt.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801. 109)

OR

Over-The-Counter Use

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



510(k) Number K022553