

K12 1573

SEP 10 2012

510(k) Summary

807.92(a)(1) – Submitter Information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro NJ 08536
Phone Number	(609) 936-3634
Fax Number	(609) 275-9445
Establishment Registration Number	3003418325
Name of Contact Person	Erin Doyle
Date Prepared	May 25, 2012
807.92(a)(2) – Name of device	
Trade or Propriety Name	Integra™ Camino® ICP Monitor
Common or Usual Name	Intracranial pressure monitor
Classification Name	Intracranial pressure monitoring device
Classification Panel	Neurology
Regulation	Class II, under 21 CFR 882.1620
Product Code(s)	GWM
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
Camino® Multi Parameter Monitor – K962928	
807.92(a)(4) - Device description	
<p>The Integra® Camino® ICP Monitor is a compact, portable device that provides tools for continuously determining and monitoring intracranial pressure (ICP) and intracranial temperature (ICT) directly in the brain, depending on which catheters are connected to the system. This monitor supports Integra fiberoptic and strain gauge catheters.</p> <p>The Integra Camino ICP Monitor displays both ICP and temperature in numeric format. The device also displays real-time ICP waveform data. It will store the mean ICP trend data from the most recent 5 days. The user can elect to extract the ICP trend data stored on the Monitor to an external memory device or stream the data to a compatible PC via the USB output. The device also provides analog output for display on compatible bedside monitors.</p>	
807.92(a)(5) – Intended Use of the device	
Indications for Use	The Integra Camino ICP Monitor is indicated for use by qualified neurosurgeons or neurointensivists for measurement of intracranial pressure and temperature.
807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate	
<p>The design of both the modified device and the predicate device is similar. Both of the devices receive signals from the catheters that are then translated into the intracranial pressure & temperature reading. These readings are then displayed on the screen for the health care practitioners to use as additional information in treatment of the patient.</p>	

Integra™ Camino® ICP Monitor and the predicate device have similar intended uses, indications for use, technology, environment for use, device classifications, product codes and measurable parameters as outlined in the substantial equivalence chart and discussion. There are no differences between the proposed device and the predicate device that raise any new safety and efficacy concerns.	
Product Characteristics	Comparison Integra™ Camino® ICP Monitor to the predicate Camino® Multi Parameter Monitor
Parameter Display	Similar
Data Output	Similar
Bedside Output	Similar
System Performance Requirements	Similar
Alarms	Similar
Parameter Indicators	Similar
User Inputs	<ul style="list-style-type: none"> • Integra™ Camino® ICP Monitor – Touch screen • Camino® Multi Parameter Monitor – Membrane Buttons
Portability and Handling	Similar
807.92(b)(1-2) – Nonclinical Tests Submitted	
The Integra Camino ICP Monitor tested in accordance with the relevant test plans/reports included with this 510(k) submission using the production equivalent units prior to release to market. Testing was performed to ensure that the device met requirements specifications and to ensure that hazard mitigations functioned as intended.	
Testing includes but is not limited to the following:	
<ul style="list-style-type: none"> • ICP Accuracy • Temperature Accuracy • Alarm setting, accuracy, volume etc. • Trend functionality • Data Export Functionality (bedside monitor, external storage) • Fault testing • Electromagnetic Compatibility • Electrical Safety • Environmental Testing • Cleaning Testing 	
807.92(b)(3) – Conclusions drawn from non-clinical data	
All necessary testing has been completed for the Integra Camino ICP Monitor and the test results support the conclusion that all Design Inputs (requirements and specifications) have been met. Testing confirmed The Integra Camino ICP Monitor is safe and effective under the proposed conditions of use and is substantially equivalent to the predicate device.	



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Integra LifeSciences Corporation
% Mr. Erin Doyle
Regulatory Affairs Associate
311 Enterprise Drive
Plainsboro, NJ 08536

SEP 10 2012

Re: K121573
Trade Name: Integra™ Camino® ICP Monitor
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: Class II
Product Code: GWM
Dated: August 2, 2012
Received: August 3, 2012

Dear Mr. Doyle:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121573

Indications for Use

510(k) Number (if known): K121573

Device Name:

Integra™ Camino® ICP Monitor

Indications For Use:

The Integra Camino ICP Monitor is indicated for use by qualified neurosurgeons or neurointensivists for measurement of intracranial pressure and temperature.

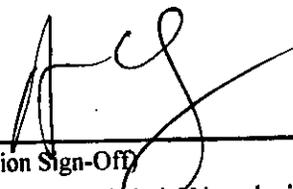
Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use
(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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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