MAR 0 6 2014

K133754

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	781-565-1347
Fax Number	781-238-0645
Establishment Registration Number	3003418325
Name of Contact Person	Elizabeth McMeniman, Senior Regulatory Affairs Specialist
Date Prepared	December 6, 2013
807.92(a)(2) – Name of device	
Trade or Propriety Name	Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit (for Catheter and Accessories)
Common or Usual Name	Ventricular Catheter Intracranial Pressure Monitoring System
Classification Name	Device, Monitoring, Intracranial Pressure
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	
Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit with Integra™ Camino® Flex Adapter K121159	
807.92(a)(4) - Device description	
The Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit functions as an entire system that includes the following: Integra Camino Flex Ventricular Catheter Monitoring Kit (Catheter and Accessories) and Integra Camino Flex Adapter (Adapter and Extension Cable), in which the Integra Camino Flex Adapter connects to the previously cleared Integra Camino Advanced Monitor (K962928 Integra LifeSciences Corporation) or to Integra Camino ICP Monitor (K121573 Integra LifeSciences Corporation). The Integra Camino Flex Ventricular Intracranial Pressure Monitoring Kit is indicated when direct and continuous intraventricular intracranial pressure (ICP) monitoring and cerebrospinal fluid (CSF) drainage are required. The device is a single use, disposable product. The device is	

comprised of a highly flexible catheter with a tensile member, a pressure sensing tip, an electrical connection to a monitor, and a drainage lumen to allow fluid connection to an extraventricular drainage (EVD) device. The device is designed for the tunneling surgical method and the kit includes the necessary accessories for access and implantation of the catheter.

The tip of the Integra Camino Flex Ventricular Catheter is implanted within the anterior horn of the left or right lateral cerebral ventricle. A cylindrical volume with a height of at least 11 mm and a diameter of at least 5 mm are required for catheter implantation.

The Integra Camino Flex Ventricular Catheter in an MR environment is for conditional use in 1.5 Tesla (T) and 3.0 T MR Environments. The conditions for safe use are:

- Not to exceed a maximum head or whole body averaged specific absorption rate (SAR) of 2 Watts/kg.
- Not to exceed maximum scan duration of 15 minutes.
- Circularly coil the externalized portions of the catheter within a 2.5 inch (6.3cm) to 3.5 inch (8.8cm) diameter range and securely tape it over the top of the patient's head.
- Use only the following coils for MRI procedures:
  - Transmit Body/Receive Body RF Coils
  - Transmit Body Coils with any Receive-Only Coil (including receive-only head coils)
- Do not use transmit head coils for MRI procedures
- None of the catheter accessories, such as the trocar, stylet, drill, drill stop and hex wrench should be brought into the MR environment. These accessories are only required during catheter placement and not needed in the MR environment.

807.92(a)(5) – Intended use of the device

Indications for Use	Use of the Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring is indicated when direct and continuous intraventricular intracranial pressure (ICP) monitoring and cerebrospinal fluid (CSF) drainage are required.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit is a labeling modification to add MR safety information to the product labeling. The technological characteristics are the same as there is no change to the product except for labeling.

The Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit and the predicate device have the same device classification, product code and measureable parameters as outlined in the substantial equivalence chart and discussion.

807.92(b)(1-2) – Nonclinical tests submitted
The Integra™ Camino® Flex Ventricular Catheter was tested in accordance with the relevant test plans/reports included in the 510(k) submission. Testing was performed to ensure that the device met pre-defined performance and safety specifications and to ensure that hazard mitigations functioned as designed. Testing includes Magnetic Resonance testing only to demonstrate MR compatibility for the catheter.
807.92(b)(3) – Conclusions drawn from non-clinical data
All necessary testing has been completed for the Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Catheter and the test results support the conclusion that all Design Inputs (requirements and specifications) have been met. Testing confirmed that the Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Catheter is safe and effective for use in an MR environment under conditions specified in the product labeling and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 6, 2014

Ms. Elizabeth McMeniman
Senior Regulatory Affairs Specialist
Integra Life Sciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536

Re: K133754
Trade/Device Name: Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring System
Regulatory Class: Class II
Product Code: GWM
Dated: December 6, 2013
Received: December 9, 2013

Dear Ms. McMeniman:

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 contact 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. 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,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133754

Device Name
Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit

Indications for Use *(Describe)*
Use of the Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit is indicated when direct and continuous intraventricular intracranial pressure (ICP) monitoring and cerebrospinal fluid (CSF) drainage are required.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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