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

December 6, 2016

Integra Lifesciences Corporation
Timothy Connors
Senior Regulatory Affairs Associate
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K160811
Trade/Device Name: CRW Stereotactic System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 4, 2016
Received: November 7, 2016

Dear Mr. Connors:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
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 below.

510(k) Number *(if known)*
K160811

Device Name
CRW Stereotactic System

Indications for Use *(Describe)*
The CRW Stereotactic System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.

Localization is performed using CT or MR imaging.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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	609-936-5531
Fax Number	NA
Establishment Registration Number	3003418325
Name of Contact Person	Timothy Connors, Senior Regulatory Affairs Specialist
Date Prepared	March 24, 2016
807.92(a)(2) – Name of device	
Trade or Propriety Name	CRW™ Stereotactic System
Common or Usual Name	Universal Compact Head Ring Luminant Localizer Frame Disposable Head Ring Screws
Classification Name	Neurological Stereotaxic Instrument
Classification Panel	Neurology
Regulation	882.4560
Product Code(s)	HAW
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
CRW-1 SYSTEM; K944463	
807.92(a)(4) - Device description	

Part of the CRW™ Stereotactic System is comprised of the following components:

- Universal Compact Head Ring (UCHR),
- Luminant Localizer Frame (LL01)
- Disposable Head Ring Screws (DHRSS- Short, DHRSL- long)

The Universal Compact Head Ring is placed on the patient and secured with the Disposable Head Ring Screws. The Luminant Localizer Frame is then attached to the base ring and the patient is taken to the neuroradiology department where a CT or MR imaging is performed. The image obtained in conjunction with the localizer allows the neurosurgeon to compute the exact three dimensional position of the region of interest.

807.92(a)(5) – Intended use of the device	
Indications for Use	The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy. Localization is performed using CT or MR imaging.
807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate	
The CRW™ Stereotactic System design is not changing as a result of this submission; this submission is primarily for a labeling change to add an MR Conditional claim and associated MRI safety information. CRW Stereotactic System and the predicate device have the same device classification, product code and measureable parameters as outlined within the submission.	
807.92(b)(1-2) – Nonclinical tests submitted	
CRW Stereotactic System was tested in accordance with FDA's Guidance: *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance Environment* (August 21, 2008) and the relevant ASTM Standards covered in the guidance document. Testing includes Magnetic Resonance testing only to support an MR conditional claim for components used in the MR environment. Additional tests to support sterilization information, shelf life information and biocompatibility have also been included. The table below outlines the testing performed, test method summary and the results of the testing.	

Test	Test Method Summary	Results
MR testing	Testing on the device assembly was executed per the suite of ASTM standards called out in the FDA Guidance regarding passive implants in the MR environment. Standards used for testing include ASTM F2052, ASTM F2213, ASTM F2182 and ASTM F2119.	Results met pre-established acceptance criteria. MR labeling included in the submission is in compliance with FDA Guidance and ASTM F2503. The results demonstrate substantial equivalence by complying with current FDA Guidance and consensus standards requirements.
Sterilization – Devices provided to the user sterile	Testing was executed on the worst-case sample from a device family to demonstrate the subject devices could be sterilized to the SAL of 10^{-6}. The testing was performed in accordance with FDA Guidance regarding devices packaged sterile.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of sterility for devices provided to the user sterile.
Sterilization – Devices to be sterilized by the end user	Three different types of end user sterilization cycles were tested to demonstrate the cycles could sterilize the devices to the SAL of 10^{-6}: EtO, steam and Sterrad®.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of sterility for devices intended to be sterilized by the end user.
Shipping/Stability	The worst-case sample was identified of those devices provided to the user sterile. Ship testing and stability testing were executed according to ASTM D4169 and ASTM F1980 to support a three-year shelf life claim.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device of the sterile device packaging in terms of shipping integrity and stability.

Biocompatibility	Biocompatibility testing was executed for patient contacting devices, as identified in ISO 10993-1, per ISO 10993-5, ISO 10993-10 and ISO 10993-11.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of biocompatibility.

807.92(b)(3) – Conclusions drawn from non-clinical data

All necessary testing has been conducted per ASTM standards for the relevant CRW Stereotactic System components to be used in an MR environment (1.5 T and 3.0 T) and the test results support the addition of an MR conditional claim to the device labeling. All other testing performed raised no additional concerns of safety or efficacy. In conclusion, the components are safe and effective for use under conditions specified in the product labeling and the device is substantially equivalent to the predicate device.