January 20, 2019

Integra LifeSciences Corp.
Jocelyn Raposo
Associate Director, Regulatory Affairs
11 Cabot Blvd
Mansfield, Massachusetts 02048

Re: K183581
Trade/Device Name: Codman Disposable Perforators
Regulation Number: 21 CFR 882.4305
Regulation Name: Powered Compound Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: HBF
Dated: December 20, 2018
Received: December 21, 2018

Dear Jocelyn Raposo:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183581

Device Name
Codman Disposable Perforator

Indications for Use *(Describe)*
The Codman Disposable Perforator is for use in perforating the cranium. When properly used, it is designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point.

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."

Section 5 – 510(k) Summary

I. Submitter

Integra LifeSciences Corp.
11 Cabot Blvd.
Mansfield, MA 02048

Establishment Registration Number: 1226348

Primary Contact: Jocelyn Raposo
Phone: (781) 971-5688

Secondary Contact: Jennifer Siu
Phone: (781) 971-5692

Date of Preparation: December 19, 2018

II. Device(s)

Device Proprietary Name	Codman Disposable Perforators
Common Name	Perforators
Classification Name	Drills, Burrs, Trephines & Accessories (Compound, Powered) (21 CFR 882.4305)
Regulatory Classification	II
Product Code	HBF

III. Predicate Device(s)

The predicate devices for this submission are:

510(k) Number	Date Cleared	Title
K791101	Aug. 28, 1979	Codman Disposable Perforator (14mm)
K071931	Oct. 22, 2007	Codman Disposable Perforators (11mm & 9mm)

IV. Device Description(s)

The Codman Disposable Perforators are pre-assembled, single-use, sterile devices that are designed to perforate the cranium. When properly used, the Disposable Perforators are designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point. They are designed with a Hudson end and are available in three color-coded sizes:

- 14mm (blue ABS sleeve) – product number: 26-1221
- 11mm (green ABS sleeve) – product number: 26-1222
- 9mm (yellow ABS sleeve) – product number: 26-1223

V. Indications for Use

The Indications for Use statement of the proposed device remains identical to the predicate devices'.

Equivalence Comparison	Codman Disposable Perforators (Predicates)	Codman Disposable Perforators (Subject of This Submission)
Indications for Use	The Codman Disposable Perforator is for use in perforating the cranium. When properly used, it is designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point.	The Codman Disposable Perforator is for use in perforating the cranium. When properly used, it is designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point.

VI. Comparison to Predicate Device

The proposed Codman Disposable Perforators are identical to the currently marketed Codman Disposable Perforators (K791101 & K071931) except for the alternate gamma irradiation sterilization cycle proposed in this 510(k). The indications for use, design, principle of operation, performance, packaging, and shelf life remain identical to the predicate devices.

Substantial Equivalence Comparison		
Characteristic	**Codman Disposable Perforators (Predicates)**	**Codman Disposable Perforators (Subject of This Submission)**
Manufacturer	Codman & Shurtleff, Inc.	Identical
Classification Panel	Neurology	Identical
Classification Name	Drills, Burrs, Trephines & Accessories (Compound, Powered) (21 CFR 882.4305)	Identical
Indications for Use	The Codman Disposable Perforator is for use in perforating the cranium. When properly used, it is designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point.	Identical
Operating Principle	With adequate pressure applied on the perforator point, engagement should occur as the Hudson End is rotated in a driver. Once pressure is removed from the drill point the device is designed to disengage.	Identical
Implant	No	Identical
Single Use Only	Yes	Identical

Substantial Equivalence Comparison		
Characteristic	**Codman Disposable Perforators (Predicates)**	**Codman Disposable Perforators (Subject of This Submission)**
Design	9 mm Perforator consisting of outer and inner body drill, drill driver, compression spring, drive pin, molded sleeve, snap bearing, flanged nyliner	Identical
	11mm Perforator consisting of outer and inner body drill, drill driver, compression spring, drive pin, molded sleeve, snap bearing, flanged nyliner	Identical
	14mm Perforator consisting of outer and inner body drill, drill driver, compression spring, drive pin, molded sleeve, snap bearing, flanged nyliner	Identical
Shelf Life	5 years	Identical
Sterilization Method	Gamma	Identical
Sterility Assurance Level (SAL)	10^{-6}	Identical
Packaging	PETG Blister Tray with heat-sealed lid placed into a unit box	Identical

VII. Performance Data

There were no changes made that affect the Codman Disposable Perforators' indications for use, principle of operation, performance, packaging, or shelf life. The only difference between the predicate and proposed devices is the use of an alternate gamma irradiation sterilization cycle to sterilize the products. There is no change to the sterilization dose parameters (25kGy-50kGy). The products continue to meet a SAL of 10^{-6} with the new cycle. A full dose mapping study has been performed to ensure there are no new issues relating to the safety or effectiveness of the products.

Please see the Summary of Testing table below for acceptance criteria and testing results.

Table Summary of Testing			
Test	Test Method / Purpose	Acceptance Criteria	Result
Full Dose Mapping Validation	Establish a new gamma radiation sterilization cycle in compliance with ISO 11137-1	Dose Uniformity Ratio: <2	Pass

Animal Testing:
No animal studies were required based on similarities of the proposed device to the predicate device and from the results of the sterilization validation.

Clinical Testing:
No clinical studies were required based on similarities of the proposed device to the predicate device and from the results of the sterilization validation.

Conclusion:
Results from the dose mapping study have demonstrated that the alternate sterilization cycle is suitable and does not raise new issues of safety and effectiveness for the finished devices. Based on the indications for use, fundamental scientific technology and a comparison to the predicate devices, the subject Codman Disposable Perforators are substantially equivalent to the predicate devices.