November 27, 2018

Integra LifeSciences Corporation
Ms. Jennifer Siu
Sr. Regulatory Affairs Specialist
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K182801
Trade/Device Name: Codman Electrosurgical Irrigator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 28, 2018
Received: October 2, 2018

Dear Ms. Siu:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2018.11.27 14:59:06 -05'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K182801

Device Name
Codman® Electrosurgical Irrigator

Indications for Use *(Describe)*
The Codman Electrosurgical Irrigator is indicated to provide flow of irrigation fluid to the tips of bipolar irrigating forceps during electrosurgery.

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.

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510(k) Summary

I. Submitter

Integra LifeSciences Corporation
11 Cabot Boulevard
Mansfield, MA 02048

Contact
Miss Jennifer Siu, Neuroscience, B.S.
Sr. Regulatory Affairs Specialist
jennifer.siu@integralife.com
(781) 971-5692

Date of Submission: September 28, 2018

II. Device

Device Proprietary Name	Codman® Electrosurgical Irrigator
Common Name	Irrigator
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400)
Regulatory Classification	II
Product Code	GEI
Review Panel	General & Plastic Surgery

III. Predicate Device

The predicate device for this submission is the Malis™ Irrigation Module 1000 (K033499), which was cleared on November 28, 2003.

IV. Device Description

The Codman Electrosurgical Irrigator is a reusable, non-sterile electrosurgical device, for use in electrosurgery to deliver irrigation fluid to tissue. The irrigator is part of an electrosurgical system consisting of an electrosurgical generator connected via an interconnecting cable, and a pair of bipolar irrigating forceps connected via a cord and tubing set.

V. Indications for Use

The Codman Electrosurgical Irrigator is indicated to provide flow of irrigation fluid to the tips of bipolar irrigating forceps during electrosurgery.

VI. Comparison to Predicate Device

The Codman Electrosurgical Irrigator is substantially equivalent to the predicate device, the Malis Irrigation Module 1000. The subject device has the same intended use and clinical utility, and similar design and operating principles, accessories, and patient/user interface as the predicate device. The

table below provides a comparison between the subject device and the predicate device.

Comparison of the Predicate and Subject Device		
	Predicate Device: Malis Irrigation Module 1000 (K033499)	**Subject Device: Codman Electrosurgical Irrigator (This Submission)**
FDA Product Code	GEI	Same as predicate
Classification	Class II - 21 CFR 878.4400	Same as predicate
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories	Same as predicate
Intended Use	To deliver irrigation fluid to the tips of bipolar irrigating forceps	Same as predicate
Reusable	Yes	Same as predicate
Flow Settings	0 - 20	Same as predicate
Flow Performance	Slow drip to constant stream	Same as predicate
Method of Operation	Peristaltic pump	Same as predicate
Irrigator Features	LED display Single irrigation knob Peristaltic pump Cut/Coag irrigation toggle	LED display Single irrigation knob Peristaltic pump Pause button
Material	Non-patient contacting	Same as predicate
Supply Voltage	100-230 VAC	100-240 VAC
Supply Frequency	50/60 Hz	Same as predicate
Supply Current	0.60 A	1.0 A
AC Powered	Yes	Same as predicate
Electrical Safety Testing	IEC 60601-1 IEC 60601-1-2	Same as predicate
Software Level of Concern Classification	Minor	Moderate
Non-Sterile	Yes	Same as predicate
Packaging	Polybags Foam inserts Mailer Carton	Same as predicate
Accessories	Power cords Interconnecting cable	Same as predicate

VII. Performance Data

The following performance data has been provided in support of the substantial equivalence determination. All testing was performed on final devices unless otherwise specified.

Bench Testing

Performance bench testing was conducted in alignment with FDA's guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued August 15, 2016 and internal requirements.

Performance Bench Test Results	
Test	**Conclusion**
Design Verification Testing	Pass
Flow Accuracy Testing	Pass
Summative Study	Pass
Nurse Design Validation Study	Pass
Surgeon Design Validation Study	Pass

Software Testing

Software testing was conducted in accordance with FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* issued May 11, 2005.

Software Verification Test Results	
Test	**Conclusion**
Software Unit Verification Testing	Pass
Software Integration and System Verification Testing	Pass

Electrical Safety/Electromagnetic Compatibility Testing

Electrical safety and EMC testing were conducted in accordance with IEC 60601-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* and IEC 60601-1-2 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*.

Electrical Test Results	
Test	**Conclusion**
IEC 60601-1:2005/A1:2012/C1:2012, Edition 3.1	Pass
IEC 60601-1-2:2014, Edition 4.0	Pass

Sterilization

The Codman Electrosurgical Irrigator is a non-sterile capital equipment and is not intended to be sterilized. Therefore, sterilization is not applicable for this device. A validation was performed to support cleaning instructions in the device labeling (Instructions for Use) in accordance with FDA's Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* issued March 17, 2015.

Shelf-Life Testing

The Codman Electrosurgical Irrigator is a reusable, non-sterile device. Therefore, there is no expiry date and shelf-life is not applicable for this device.

Biocompatibility Testing
The Codman Electrosurgical Irrigator is a non-patient contacting device. Therefore, biocompatibility is not applicable for this device.

Animal Studies
No animal studies were performed as appropriate verification and validation of the subject device was achieved based on the comparison to the predicate device and from the results of the bench, software, and electrical/safety testing.

Clinical Studies
No clinical studies were performed as appropriate verification and validation of the subject device was achieved based on the comparison to the predicate device and from the results of the bench, software, and electrical/safety testing.

VIII. Conclusion

Based upon the intended use, design, operating principles, patient/user interface, comparison to the predicate device, and testing conducted, it is concluded that the subject device, Codman Electrosurgical Irrigator, is substantially equivalent to the predicate device, Malis Irrigation Module 1000 (K033499), and therefore does not raise different questions of safety and effectiveness.
