May 14, 2021

Integra MicroFrance
c/o Ms. Malena Zammetti
Regulatory Affairs Specialist II
Integra LifeSciences Corporation
1100 Campus Rd.
Princeton, NJ 08540

Re: K210942
Trade/Device Name: MicroFrance Monopolar and Bipolar Electrosurgical Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI,
Dated: March 29, 2021
Received: March 30, 2021

Dear Ms. Zammetti:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210942

Device Name
MicroFrance® Bipolar and Monopolar Electrosurgical Instruments

Indications for Use *(Describe)*
The electrosurgical instruments are intended to remove tissue and/or control bleeding.

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.

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510(k) Summary

I. Submitter Information	
Submitter	Integra LifeSciences Corporation 1100 Campus Rd. Princeton, NJ, USA 08540 On behalf of: Integra MicroFrance Le Pavillon, Saint Aubin Le Monial Allier, 03160 France Contact: Olivier Doizon, Manager, Quality +33 (0) 470 67 98 0 olivier.doizon@integralife.com
U.S. Contacts:	Primary Contact: Ms. Malena Zammetti Regulatory Affairs Specialist II 717-818-8774 malena.zammetti@integralife.com Secondary Contact: Ms. Jocelyn Raposo Director, Regulatory Affairs 508-813-7015 Jocelyn.Raposo@integralife.com
Establishment Registration Number:	9680837
Date 510(k) Summary Prepared:	May 14, 2021
II. Device	
Trade or Propriety Name:	MicroFrance® Bipolar and Monopolar Electrosurgical Instruments
Common or Usual Name:	Electrosurgical cutting and coagulation accessories
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Panel:	General and Plastic Surgery
Regulation:	Class II, 21 CFR 878.4400
Product Code:	GEI

III. Predicate Device

The predicate devices for this submission are the MicroFrance Electrosurgical Instruments, K993655, which were cleared on 12/21/1999.

IV. Device Description

The MicroFrance® Bipolar and Monopolar Electrosurgical Instruments consist of forceps, probes, knives, suction tubes, hooks, elevators and picks used for laparoscopic or endoscopic access and open surgery. These electrosurgical instruments are reusable and available in unibody (one-piece) and dismantlable (modular) designs. They are used as part of an electrosurgical system consisting of a generator and cord attached to the proximal end of the devices to provide power and deliver electrical current from the generator to the distal tips of the devices.

V. Indications for Use

The electrosurgical instruments are intended to remove tissue and/or control bleeding.

VI. Comparison of Characteristics with the Predicate Devices

The MicroFrance® Bipolar and Monopolar Electrosurgical Instruments are substantially eqivalent to the predicate devices, the Micro-France Electrosurgical Instruments. The subject devices have the same indications for use, operating principles, clinical utility and similar design specifications and materials as the predicate devices. To comply with the latest electrical safety and EMC standards, material changes and minor componenet changes were made. The componenet changes include minor dimensional changes to subassemblies to ensure proper final assembly of the subject devices and to maintain the same finished dimensional specifications as the predicate devices. The table below provides a comparison between the subject devices and the predicate devices.

Comparison of the Predicate and Subject Device			
	Predicate Device: Micro-France Electrosurgical Instruments, Various (K993655)	**Subject Device: MicroFrance® Bipolar and Monopolar Electrosurgical Instruments (This Submission)**	**Difference and Justification**
FDA Product Code	GEI	Same as predicate	No difference
Classification	Class II – 21 CFR 878.4400	Same as predicate	No difference
Classification Name	Electrosurgical cutting and coagulation device and accessories	Same as predicate	No difference
Indications for Use	The electrosurgical instruments are used to remove tissue and/or control bleeding.	Same as predicate	No difference
Type	Various dismantlable (modular) and unibody bipolar and monopolar instruments	Same as predicate	No difference
Device Sterility	Non-Sterile	Same as predicate	No difference
Reusable	Yes	Same as predicate	No difference
Reprocessing Methods (cleaning and sterilization)	Manual and Automated cleaning and Steam sterilization	Same as predicate	No difference
Design	Multiple bipolar and monopolar instrument	Changes to the insulation coating materials and thickness;	The performance, electrical safety and EMC test results

	designs as cleared per K993655	changes to the monopolar pin connector and bipolar screw set alignment; and Minor dimensional changes to subassembly components to accommodate increase in thickness of Rislan insulation coating.	demonstrate that the subject devices do not raise any new questions of safety and are substantially equivalent to the predicate devices.
Materials	Materials as cleared per K993655	Materials remain the same as the predicate device except for the insulation coating and the bipolar connector material Insulation coating: From Rislan® ES BLUE 7413 M (Blue Polyamide) to Rislan® ESY BLUE 7414 (Blue Polyamide) Bipolar connector: From PEEK (Polyether ether ketone) to Propylux® (Polypropylene) Monopolar Connector: Connector pin is partially coated with Rislan® ESY BLUE 7414	The performance, electrical safety, EMC, and biocompatibility test results demonstrate that the subject devices do not raise any new questions of safety and effectiveness and are substantially equivalent to the predicate devices.
Packaging	Packaging types as cleared per K993655	Same as predicate	No difference

VII. Performance Data

The following bench, electrical safety, electromagnetic compatibility (EMC), and biocompatibility testing has been performed in support of the substantial equivalence determination.

Performance Bench Testing		
Test	**Test Method Summary**	**Results**
Lesion Size	To demonstrate the subject devices, monopolar and bipolar, are effective for their intended use by evaluating coagulation performance.	Results from side-by-side testing of the predicate and subject devices prior to reprocessing showed no significant difference in the lesion size. supporting substantial equivalence between the subject and predicate devices. Test results of the subject device after 150 reprocessing cycles demonstrates that the subject device continues to meet user requirements.
Thermal Effects on Lesion Study	To characterize the performance of the subject devices by measuring the typical lesion size (length, width and depth) they generate on a range of tissue densities (heart, liver and kidney) at three power settings: minimal, default and maximal.	All test samples, at various power settings, on three different tissue types showed coagulation was effectively applied by the subject devices, supporting substantial equivalence between the subject and predicate devices.
Physical Characterization	Perform a visual inspection of the physical characteristics for defects.	No defects were observed on the subject devices during the visual inspection of the physical characteristics, supporting substantial equivalence between the subject and predicate devices.
Dimensional Verification	Measure the device attributes and confirm they are within defined	All measured dimensions are within defined tolerances and specifications for the subject

	tolerances and specifications.	devices, supporting substantial equivalence between the subject and predicate devices.
Functional Testing	Verify key functionality of the subject devices remains similar to the predicate devices.	All test samples passed the acceptance criteria for key functionality of the subject devices, supporting substantial equivalence between the subject and predicate devices.
Electrical and Mechanical Testing	Verify no failures occur during electrical and resistivity testing of the subject devices. Measure the applied closing forces are similar for the subject and predicate devices.	All test samples passed the acceptance criteria for electrical, resistivity and applied closing force testing of the subject devices, supporting substantial equivalence between the subject and predicate devices.
Biocompatibility Testing		
Test	**Test Method Summary**	**Results**
Cytotoxicity Study using the ISO Elution Method (1X MEM) ISO 10993-5	To evaluate the potential cytotoxic effect of a test article extract using an in vitro mammalian cell culture.	All products tested passed the acceptance criteria demonstrating that the devices are biocompatible and therefore are substantially equivalent to the predicate devices.
ISO Guinea Pig Maximization Sensitization Test ISO 10993-10	To evaluate the potential of the test article extracts to cause delayed dermal contact sensitization in the guinea pig.	All products tested passed the acceptance criteria demonstrating that the devices are biocompatible and therefore are substantially equivalent to the predicate devices.
ISO Intracutaneous Study in Rabbits ISO 10993-10	To evaluate the potential of test article extracts to induce local dermal irritation following intracutaneous injection in rabbits.	All products tested passed the acceptance criteria demonstrating that the devices are biocompatible and therefore are substantially equivalent to the predicate devices.
Acute Systemic Toxicity ISO 10993-11	To evaluate the acute systemic toxicity of the test article extracts following intravenous or intraperitoneal injection in mice.	All products tested passed the acceptance criteria demonstrating that the devices are biocompatible and therefore are substantially equivalent to the predicate devices.
Chemical Characterization of Extractables ISO 10993-18	To perform a chemical characterization to identify and quantitate the extractables and/or leachables that may be released from the test articles.	Extractables were identified and quantified, any extractables above the Quantification Limit (QL) underwent a toxicological risk assessment and were deemed to be clinically acceptable.
Toxicology Risk Assessment ISO 10993-17	To assess extractables identifed during chemical characterization testing.	Based on the chemical results evaluated in the toxicological risk assessments, the risk of induced toxicity during clinical use of the subject devices had been deemed to be clincially acceptable.

Bench Testing

Performance bench testing was conducted in alignment with the FDA's guidance document, "*Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery"* issued March 9, 2020, and included the following testing: lesion size, thermal effects on lesion study, physical characterization, dimensional verification, functional, electrical and mechanical testing. Lesion size testing of the predicate and subject devices prior to reprocessing showed no significant difference in the lesion size between the subject and predicate devices. Test results of

the subject device after 150 reprocessing cycles demonstrates that the subject device continues to meet user requirements. Thermal effects testing was performed using three tissue types (heart, liver and kidney). All test samples, at various power settings, on the three different tissue types showed coagulation was effectively applied by the subject devices. No defects were observed on the subject devices during the visual inspection of the physical characteristics. The dimensional verification confirmed that all measured dimensions are within defined tolerances and specifications for the subject devices. All functional testing samples passed the acceptance criteria for key functionality of the subject devices. The electrical and mechanical test samples passed the acceptance criteria for electrical, resistivity and applied closing force. These bench test results demomstrate substantial equivalence between the subject and predicate devices.
Electrical safety and electromagnetic compatibility (EMC)
EMC and electrical safety testing were conducted in accordance with IEC 60601-1-2:2014, Edition 4.0, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*, ANSI/AAMI/ES60601-1:2005/ (R)2012 and A1:2012, C1:2009/ (R)2012 and A2:2010/(R)2012, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)*, AAMI/ANSI/IEC 60601-2-2:2017, Edition 6.0, *Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*, IEC 60601-1-6:2013, Edition 3.1, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*, and IECO 60601-2-18:2009, Edition 3.0, *Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*. The MicroFrance® Bipolar and Monopolar Electrosurgical Instruments passed all EMC and electrical safety testing.
Software Verification and Validation Testing
The MicroFrance® Bipolar and Monopolar Electrosurgical Instruments do not contain software.
Biocompatibility Testing
Biocompatibility testing was conducted in accordance with ISO 10993-1:2018, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process* and FDA's guidance documents, *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process"* issued September 4, 2020 and *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued March 9, 2020.
Animal Studies
No animal studies were performed, as appropriate verification and validation of the changes was achieved based on the comparison to the predicate devices and from the results of the bench testing, biocompatibility evaluation, electromechanical compatibility (EMC), and electrical safety testing.
Clinical Studies
No clinical studies were performed, as appropriate verification and validation of the changes was

achieved based on the comparison to the predicate devices and from the results of the performance testing, biocompatibility evaluation, electromechanical compatibility (EMC), and electrical safety testing.
VII. Conclusions
The proposed MicroFrance® Bipolar and Monopolar Electrosurgical Instruments are identical in intended use, indications, operating principles, technology, and clinical utility compared to the predicate devices. The changes to the subassembly dimensional specifications and material specifications have been verified and validated. The test results demonstrate that the subject devices do not raise new questions of safety and effectiveness and are substantially equivalent to the predicate devices.