DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 21, 2016

Jeisys Medical Incorporated
c/o Ms. Priscilla Chung
LK Consulting Group USA, Inc.
2651 E. Chapman Ave., Ste 110
Fullerton, CA 92831

Re: K153727
Trade/Device Name: INTRAcel Premium Fractional RF Micro Needle (FRM) System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical, cutting and coagulation device & accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 7, 2016
Received: June 17, 2016

Dear Ms. Chung:

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" (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 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,

Christopher J. Ronk -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153727

Device Name

INTRAcel Premium Fractional RF Micro Needle (FRM) System

Indications for Use *(Describe)*

The INTRAcel Premium Fractional RF Micro Needle (FRM) System device is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

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
(K153727)

1. Submission Sponsor

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Korea
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2. Submission Correspondent

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3. Date Prepared

July 19, 2016

4. Device Identification

Trade/Proprietary Name:	INTRAcel Premium Fractional RF Micro Needle (FRM) System
Common/Usual Name:	Electrosurgical coagulation device and accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	878.4400
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

5. Predicate Devices

Lutronic – INFINI, K121481

6. Device Description

The INTRAcel Premium consists of the following components:

- INTRAcel Premium (Main Frame)
- Active Accessory
  : 10xINTRAcelTip 1011
  1x Power cable
  1x Foot switch
  1xHandpiece
  1xHandpiece hanger
  1x User's manual

7. Intended Use

The INTRAcel Premium device is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

8. Comparison of Technological Characteristics

The INTRAcel Premium device shares the same or similar indications for use, device operation, overalltechnical and functional capabilities, and therefore is substantially equivalent to the predicate devices. The INTRAcel Premium device is similar in design and function to the predicate devices for the modes of operation and use.

The devices have a control unit that can be programmed utilized for the patient parameters. The devices are equipped with an input device either a stylus or touch screen to program the parameters. In addition, they are equipped with manual interface, enabling to operate the device during therapy, and a display, which shows the set and indicated parameters. During operation the devices have an applicator instrument attached to the main unit.

These devices all have the same intended use and indications for use as the INTRAcel Premium device. Devices use RF energy delivered through micro needle electrodes to provide treatment controlled by a user controlled interface.

9. Substantial Equivalence Discussion

The following table compares the INTRAcel Premium device to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer		Lutronic	Jeisys Medical, Inc.
Trade Name		Predicate Device INFINI	Subject Device INTRAcel Premium
510(k) Number		K121481	K153727
Intended Use		The device is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis and the percutaneous treatment of facial wrinkles.	The INTRAcel Premium is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
Design		The device uses Bipolar radiofrequency to apply heat therapy to the skin, resulting skin resurfacing and collagen remodeling for treatment of wrinkles.	The device uses Bipolar radio frequency to apply therapy for use in Dermatologic and General Surgical procedures electrocoagulation and hemostasis.
Materials		Plastic and metal enclosure with hand-piece for application	Plastic and metal enclosure with hand-piece for application
Construction		Constructed of materials that conform to safety standards and requirements	Constructed of materials that conform to safety standards and requirements
Interface		Touch screen user applied interface to program and setthe controls for the patient application; there is a hand-piece utilized to deliver the treatment	Touch screen user applied interface to program and set the controls for the patient application; there is a hand-piece utilized to deliver the treatment
Electrosurgical Unit	**Energy Source**	Radio Frequency	Radio Frequency
	Mode of Operation	Bipolar	Bipolar
	Power Source	Unknown	120 VAC, 50/60 Hz
	Frequency	1 MHz	1 MHz
	Nominal Operating Power	50W (Up to 20 Level)	12.5W (Level 1 -4), 32W (Level 5) 40.5 W(Level 6) 50 W(Level 7)
	Maximum power delivered to the patient	50W	50W
	Maximum power of per pin delivered to the patient	50W	50W
	Impedance	_	200 ohm
	Treatment temperature range	36 – 43°C	39°C - 42°C
	Treatment levels	20 Level	1 – 7 levels (1 low, 7 high)
	Dimensions	362 mm (W) x 40 mm (L) x 108 mm (H)	350 mm (W) x 400 mm (L) x 108 mm (H)
	Weight	28 kG	63 kG

	Safety features		Safety interlocks, removable key switches, hand-piece triggering, visual and audible indicators, cut-off temperature switches, emergency off button.	There are an emergency switch and a key switch so that the operator can control by touch screen based on window O/S program.
Active Accessory	**Dimensions**	**Depth of skin ablation**	0.5-3.5mm	0.5/0.8/1.5/2.0mm
		Pin thickness	0.25mm	0.25mm
		Needle Quantity	49ea	49ea
		Pin length	7.6mm	11mm
		The distance between the pin	1.3mm	1.3mm
	Material		Unknown+SUS304	ABS+SUS304
	RF treatment area		Spot Size (Treated area) : 1cm X 1cm	Spot Size (Treated area) : 1cm X 1cm
	Recommended Treatment Time		10 min	10min~15min

10. Non-Clinical Performance Data

The device's hardware and software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the deviceperforms as intended. The Device Hazard analysis was completed and risk control implemented to mitigate identified hazards. The testing result supports that all the hardware specifications and software specifications have met the acceptance criteria of each module and interaction of processes. The INTRAcel Premium device passed all testing and supports the claims of substantial equivalence and safe operation.

The INTRAcel Premium device complies with the applicable voluntary standards for Electromagnetic Compatibility and Safety. The device passed all the electrical and safety testing according tonational and international standards.

Testing Type	Test Description	Test Result
Electrical Safety and Electromagnetic Compatibility Testing	• IEC 60601-1:2012 • IEC 60601-2-2:2009 • IEC 60601-1-2:2007	The INTRAcel Premium met all acceptance criteria in accordance with IEC 60601-1:2009, IEC 60601-2-2:2009 and IEC 60601-1-2:2007.
Performance Testing	• Dimensional Inspection • Accuracy of Measurement	The INTRAcel Premium met all acceptance criteria.

Biocompatibility Testing	• Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity	The active electrodes are biocompatible.
Sterilization and Shelf Life Testing	• Ethylene Oxide Residues • Bioburden • Sterility • Bacteriostasis/Fungistasis • Shelf Life	The INTRAcel Premium met all acceptance criteria.
Software design Testing	• IEC62304:2006	The INTRAcel Premium met all acceptance criteria in accordance with IEC 62304:2006

The preclinical performance test by in-vivo micropig model was performed to investigate the wound healing response in porcine subjects after the Fractional RF Micro Needle (FRM) treatment using histopathological examination.The treatment was performed at the energy level, 0.5J, 1.25J and 3.0J and in depth ofmicroneedling0.5mm, 0.8mm, 1.5mm and 2.0mm. Histologic evaluation was done by H&E and Trichrome for immediately after, 7 days after, 14 days after, 28 days after and 10 weeks after procedure.Histologically, the thermally coagulated collagen after treatment was replaced by new collagen.
Additional preclinical performance test was performed to investigate ex-vivo animal tissue testing comparing the subject device and predicate device power delivery characteristics effect on tissue.The treatment was performed at the energy level, 0.5J, 1.25J and 3.0J in depth of microneedling0.5mmand 2.0mm. Histologic evaluation was done by H&E and Trichrome for immediately after procedure. Histologically, both Subject device and predicate device created conical diamond shaped tissue coagulation inthe dermis and show similar coagulated column. The INTRAcel Premium Fractional RF Micro Needle (FRM) System was found to be substantially equivalent to the predicate device foruseindermatological and general surgical procedures for electrocoagulation and hemostasis.

11. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate devices. However, we did clinical testing to validate safety and efficacy. It was published in the surgical corner of Journal of Drugs in Dermatology. The verification and validation testing of the device software and electrical safety and EMC testing of the device was found to acceptable and supports the claims of substantial equivalence.

12. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the difference between the INTRAcel Premium system and the predicate device do not raise any questions regarding its safety and effectiveness. The INTRAcel Premium system, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.

13. Conclusion

The INTRAcel Premium device has similar intended use and technological characteristics as the predicate devices.

The information provided in this submission supports the substantial equivalence to the predicate device.