January 15, 2020

Jeisys Medical Inc.
% Parul Chansoria
Regulatory Consultant
Elexes Medical Consulting
6494 Tralee Village Dr
Dublin, California 94568

Re: K183284
Trade/Device Name: INTRAcel RF Microneedle System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 16, 2019
Received: December 16, 2019

Dear Parul Chansoria:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183284

Device Name
INTRAcel RF Microneedle System

Indications for Use *(Describe)*
INTRAcel RF Microneedle System is indicated for use in dermatological and general surgical procedures for electrocoagulation, hemostasis and the percutaneous fractional treatment of the skin in monopolar and bipolar mode.

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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I. SUBMITTER

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Prepared: January 15, 2020
FDA Establishment Number: 3006985163

II. DEVICE

Common/Usual Name: Electrosurgical coagulation device and accessories
Trade Name: INTRAcel RF Microneedle System
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Classification Panel: General and Plastic Surgery
Product Code: GEI
Regulation Number: 21 CFR 878.4400

III. PREDICATE DEVICE

The INTRAcel RF Microneedle System is substantially equivalent to the following cleared device:

Company	Predicate Priority	Product	510(k) Number
Jeisys Medical Inc.	Primary Predicate	INTRAcel Premium Fractional RF Micro needle (FRM) System	K153727

IV. DEVICE DESCRIPTION

The INTRAcel RF Microneedle System is indicated for use in dermatological and general surgical procedures. INTRAcel RF Microneedle System comprises of two primary components; an RF Generator with User Interface Software and a disposable Electrode Insertion Device with an integrated cable.

RF Generator: RF energy is delivered from the RF Generator through the electrodes into the target tissue. Treatment is provided in bipolar mode and monopolar mode. In the monopolar mode, RF energy flows from the main unit and a patient loop is formed by pairing the active electrode (microneedle electrode) with the neutral electrode pad. Heat is not generated in a neutral electrode plate which has a low contact resistance but heat is generated in an active electrode which has a relatively large contact resistance and this heat momentarily causes tissue to heat up to cause coagulation. The bipolar RF energy is delivered between independent adjacent electrode pairs. The RF Generator is not disposable.

Electrode Insertion Device: The insertion device is a hand-held mechanical device that is used to insert the electrodes into the target tissue. It is supplied sterile, is for single patient use only and cannot be resterilized. The device has forty-nine electrodes. The device has a mechanism to deploy and retract the electrodes when actuated by the operator.

Cable: There is a cable with a connector that connects to the RF Generator. The RF Generator is the energy source for the system.

Accessories: Cables, neutral electrode pad, neutral electrode pad cable, footswitch, and power cord are also supplied with the system.

V. INDICATIONS FOR USE

INTRAcel RF Microneedle System is indicated for use in dermatological and general surgical procedures for electrocoagulation, hemostasis and percutaneous fractional treatment of the skin in monopolar and bipolar mode.

VI. TECHNOLOGICAL CHARACTERISTICS W.R.T. THE PREDICATE DEVICE

The Indications for Use, key technological characteristics of the Electrosurgical Unit (ESU) and operating principle of the Subject Device are equivalent to those of the Predicate Device.

Comparison with Primary Predicate

Parameter		Subject Device	Predicate Device	Comments
Device Name		INTRAcel RF Microneedle System	INTRAcel Premium Fractional RF Micro needle (FRM) system	
Electrosurgical Unit(ESU)	Monopolar or Bipolar	Monopolar and Bipolar	Bipolar	Different. Addition of Monopolar mode.
	Output frequency	1MHz	1MHz	Same as predicate
	Power Output	50W	50W	Same as predicate
	Voltage Output	90V	90V	Same as predicate
	Dimensions	350mm(W)x 405mm(D)x 1080mm(H)	350mm(W) x400mm(D)x1080mm(H)	Same as predicate
	Weight	63Kg	63Kg	Same as predicate
	Power Source/Input	AC 120V, 50-60Hz	AC 120V, 50/60Hz	Same as predicate

Active accessory (RF Electrode)	Monopolar or Bipolar	Monopolar and Bipolar	Bipolar	Different. Addition of Monopolar Mode
	Electrode Type	Micro Needle	Micro Needle	Same as predicate
	Physical Dimensions	Depth of skin Ablation: 0.5/0.8/2.0mm Thickness:0.25 mm (Tip of the needle:22”)	Depth of skin ablation:0.5 /0.8/2. 0mm Thickness: 0.25mm	Same as predicate
	Materials	Tip:ABS(sr-030 0)Needles: SUS304	Tip:ABS(sr -0300) Needles:S US304	Same as predicate
	Single-Use or Reusable	Single-Use	Single-Use	Same as predicate
	Sterilization	EO gas	EO gas	Same as predicate
Neutral electrode pad	Conductive or Capacitive	Conductive area: 250mm x140mm contact on the skin	Not a feature of this device	Different. Addition in the subject device for the monopolar mode.
	Single-Use or Reusable	Single-Use		
	Physical Specification	250mm(W) x 140mm(L) x0.5mm(H)		

	Materials	ABS High density Polyethene (material that is patient contacting)		
Miscellaneous accessory (Footswitch)	Functions	For emitting RF energy into electrode	For emitting RF energy into electrode	Same as predicate
	Performance	Single pole, single throw	Single pole, single throw	Same as predicate
	Physical Specification	Single pedal, IPX8	Single pedal, IPX8	Same as predicate
	Materials	Steel and plastic	Steel and plastic	Same as predicate

The following differences exist between the Subject Device and Predicate Device:

- The Subject Device operates in both monopolar and bipolar mode but the primary predicate operates only in bipolar mode.
- The Neutral Electrode Pad is an addition to the Subject Device.

VII. NON-CLINICAL STUDY

1.1. 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 that the device performs as intended. The Device Hazard Analysis was completed and risk control was

implemented to mitigate identified hazards. The test results demonstrate that all the acceptance criteria of each module and interaction of processes have been met. The Subject Device passed all testing which supports substantial equivalence and safe operation. The INTRAcel RF Microneedle System complies with the applicable voluntary standards for Electromagnetic Compatibility and Safety. The device passed all the electrical and safety testing according to national and international standards.

Tests Performed

Testing Type	Test Description	Test Result
Electrical Safety and Electromagnetic Compatibility Testing	● IEC 60601-1:2012 ● IEC 60601-1-6:2010,AMD1:2013 ● IEC 60601-2-2:2009	The INTRAcel RF Microneedle System met all acceptance criteria in accordance with IEC 60601-1:2012, IEC 60601-1-6:2010, AMDA1:2013 and IEC 60601-2-2:2009.
Performance Testing	● Performance Test Report for ESU ● INTRAcel Tip Count Test ● Verification Performance of INTRAcel Tip	The INTRAcel RF Microneedle has met the acceptance criteria.
Biocompatibility Testing	● Cytotoxicity ● Sensitization ● Intracutaneous Reactivity	The microneedle electrodes are biocompatible.
Sterilization and Shelf Life Testing	● Ethylene Oxide Sterilization	The INTRAcel RF Microneedle has

	Residuals ● Accelerated aging test	met the acceptance criteria.

VIII. SOFTWARE VERIFICATION AND VALIDATION TESTING

Software Verification and Validation Testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as "moderate" level of concern, since a failure or latent flaw in the software would not directly or indirectly result in serious injury or death to the patient or operator.

IX. ANIMAL PERFORMANCE TESTING

A study was conducted to see the wound healing response following FRM treatment for both human and porcine skin. Healing responses were observed by the time after Fractional Radiofrequency Microneedling (FRM) treatment at various energy levels. Biopsy was conducted to see the wound healing process immediately after the treatment, 2days, 14days, 28days, and 10 weeks post the treatment. H&E stain and HSP47 stain were conducted to see the changes in inflammatory cell, collagen. Also, the study has conducted RT-PCR (Reverse Transcription - Polymerase Chain Reaction) with the tissue biopsied from Micro-pig covering 10 weeks to see mRNA change of collagen, Heat Shock Proteins (HSPs), and matrix metalloproteinase (MMPs).

X. CONCLUSION

The INTRAcel RF Microneedle System is substantially equivalent to the Predicate Device in Indications for Use, key technological characteristics of the Electrosurgical Unit (ESU) and operating principle. Safety and performance testing was performed and Jeisys Medical Inc. has concluded that the Subject Device does not raise any new questions of safety and efficacy and is substantially equivalent to the predicate device.