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

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
## Indications for Use

**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)**

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

---

*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
PRASstuff@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."
510(k) Summary
(K153727)

1. Submission Sponsor

Jeisys Medical, Inc.
307 Daeryung Techno Town 8th
Gamasan-ro 96, Geumcheon-Gu, Seoul
153-775
Korea
Phone: (82) 2.2603.6417
Fax: (82) 2.2603.6447
Contact: Hyo Seok Lee, RA Manager

2. Submission Correspondent

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110,
Fullerton CA 92831
Tel: 714-202-5789
Email: juhee.c@LKconsultinggroup.com

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:
  - 10x INTRAcel Tip 1011
  - 1x Power cable
  - 1x Foot switch
  - 1x Handpiece
  - 1x Handpiece 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, overall technical 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>
<thead>
<tr>
<th>Manufacturer</th>
<th>Lutronic</th>
<th>Jeisys Medical, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade Name</strong></td>
<td>Predicate Device</td>
<td>Subject Device</td>
</tr>
<tr>
<td></td>
<td>INFINI</td>
<td>INTRAcel Premium</td>
</tr>
<tr>
<td><strong>510(k) Number</strong></td>
<td>K121481</td>
<td>K153727</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>The device is intended for use in dermatologic and general surgical procedures for electrosurgery and hemostasis and the percutaneous treatment of facial wrinkles.</td>
<td>The INTRAcel Premium is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>The device uses Bipolar radiofrequency to apply heat therapy to the skin, resulting skin resurfacing and collagen remodeling for treatment of wrinkles.</td>
<td>The device uses Bipolar radiofrequency to apply therapy for use in Dermatologic and General Surgical procedures electrocoagulation and hemostasis.</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td>Plastic and metal enclosure with hand-piece for application.</td>
<td>Plastic and metal enclosure with hand-piece for application.</td>
</tr>
<tr>
<td><strong>Construction</strong></td>
<td>Constructed of materials that conform to safety standards and requirements.</td>
<td>Constructed of materials that conform to safety standards and requirements.</td>
</tr>
<tr>
<td><strong>Interface</strong></td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Electro surgical Unit</strong></td>
<td><strong>Energy Source</strong></td>
<td>Radio Frequency</td>
</tr>
<tr>
<td></td>
<td><strong>Mode of Operation</strong></td>
<td>Bipolar</td>
</tr>
<tr>
<td></td>
<td><strong>Power Source</strong></td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td><strong>Frequency</strong></td>
<td>1 MHz</td>
</tr>
<tr>
<td></td>
<td><strong>Nominal Operating Power</strong></td>
<td>50W (Up to 20 Level)</td>
</tr>
<tr>
<td></td>
<td><strong>Maximum power delivered to the patient</strong></td>
<td>50W</td>
</tr>
<tr>
<td></td>
<td><strong>Maximum power of per pin delivered to the patient</strong></td>
<td>50W</td>
</tr>
<tr>
<td></td>
<td><strong>Impedance</strong></td>
<td>_</td>
</tr>
<tr>
<td></td>
<td><strong>Treatment temperature range</strong></td>
<td>36 – 43°C</td>
</tr>
<tr>
<td></td>
<td><strong>Treatment levels</strong></td>
<td>20 Level</td>
</tr>
<tr>
<td></td>
<td><strong>Dimensions</strong></td>
<td>362 mm (W) x 40 mm (L) x 108 mm (H)</td>
</tr>
<tr>
<td></td>
<td><strong>Weight</strong></td>
<td>28 kG</td>
</tr>
</tbody>
</table>
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 device performs 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 to national and international standards.

<table>
<thead>
<tr>
<th>Safety features</th>
<th>Test Description</th>
<th>Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety interlocks, removable key switches, hand-piece triggering, visual and audible indicators, cut-off temperature switches, emergency off button.</td>
<td>There are an emergency switch and a key switch so that the operator can control by touch screen based on window O/S program.</td>
<td></td>
</tr>
<tr>
<td>Active Accessory</td>
<td>Dimensions</td>
<td>Depth of skin ablation</td>
</tr>
<tr>
<td></td>
<td>0.5-3.5mm</td>
<td>0.5/0.8/1.5/2.0mm</td>
</tr>
<tr>
<td></td>
<td>0.25mm</td>
<td>0.25mm</td>
</tr>
<tr>
<td></td>
<td>49ea</td>
<td>49ea</td>
</tr>
<tr>
<td></td>
<td>7.6mm</td>
<td>11mm</td>
</tr>
<tr>
<td></td>
<td>1.3mm</td>
<td>1.3mm</td>
</tr>
<tr>
<td></td>
<td>Unknown+SUS304</td>
<td>ABS+SUS304</td>
</tr>
<tr>
<td>RF treatment area</td>
<td>Spot Size (Treated area) : 1cm X 1cm</td>
<td>Spot Size (Treated area) : 1cm X 1cm</td>
</tr>
<tr>
<td>Recommended Treatment Time</td>
<td>10 min</td>
<td>10min~15min</td>
</tr>
</tbody>
</table>
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 of microneedling 0.5mm, 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 microneedling 0.5mm and 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 in the 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 for use in dermatological 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.