DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 4, 2015

Jeisys Medical Incorporated
% Ms. Priscilla Chung
LK Consulting Group USA Incorporated
2651 East Chapman Avenue, Suite 110
Fullerton, California 92831

Re: K142833
Trade/Device Name: INTRAgen
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OUH GEI
Dated: April 28, 2015
Received: April 30, 2015

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 Industry and Consumer Education 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" (21CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -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)*
K142833

Device Name

INTRAgen

Indications for Use *(Describe)*

INTRAgen is intended for dermatologic and general surgical procedures for electro coagulation 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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
PRAStaff@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

[As required by 21 CRF 807.92]
(K142833)

1. Date Prepared

June 3, 2015

2. Submitter's Information

- Name of 510K Applicant / Manufacturer:

  Jeisys Medical Inc.

  307, Daeryung Techno Town 8th,
  481-11, Gasan-dong, Geumcheon-gu,
  Seoul, 153-775, Korea,

- Contact Name: KyungWon Hwang (Mr.) / RA Manager

  - Telephone No. : +82 2 2603 6417
  - Fax No. : +82 2 2603 6447
  - Email Address : lhs1436@jeisys.com

- Registration Number: 3006985163

3. Trade Name, Common Name, and Classification

- Trade Name: INTRAgen
- Common Name: Electrosurgical Unit
- Classification Name: Electrosurgical cutting and coagulation device and accessories.
- Classification Panel: General & Plastic Surgery
- Classification Regulation: 21 CFR 878.4400
- Primary Product Code: OUH
  Secondary Product Code: GEI

- Device Class: II

4. Identification of Predicate Device(s)

The identified predicate devices within this submission are shown as follow;

- 510(k) Number: K053365
- Applicant: Thermage Inc.
- Common Name: Electrosurgical Unit
- Device Name: Thermage ThermaCool System

5. Description of the Device

The INTRAgen uses the principle that coagulation of cellular tissue is caused using the heat generated by the load or contact resistance by carrying high frequency current to the body.

Active electrodes of INTRAgen have 2 types according to effective area: model KT-07 (7 mm x 7 mm) and model KT-15 (15 mm x 15 mm). Electrical current flows through the tip of the electrode, through the target tissue and to the patient plate. The active electrodes are for single use. Patient contacting materials are PCB (Polychlorinated Biphenyl) and ABS (Acrylonitrile-Butadiene-Styrene Copolymer).

The INTRAgen consists of the following components:

- INTRAgen (Main Frame)
- Active Accessory
  : Active Electrode(KT-07 (7 mm x 7 mm), KT-15 (15 mm x 15 mm)), Hand-piece Hanger and Hand-piece
- Miscellaneous Accessories
  : Foot Switch and Power Cable

6. Intended Use

The INTRAgen is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

7. Technological Characteristics

Based on a technical feature comparison, the subject device was found to have the same output frequency as the predicate devices. The design and the components of the INTRAgen including the RF generator and the handpiece applicator are similar to the predicate.

However, the subject device has a different power output, tip energy and electrode size from the predicate device. The power output of the subject device is 5 W – 136 W while that of the predicate device is 330 W. The tip energy of the subject device is 10 J – 136 J while that of the predicate device is 52 J – 220 J. The subject device has two types of tip size (7 mm x 7 mm and 15 mm x 15 mm) whereas the predicate device has three types of tip size (25 mm x 25 mm, 15 mm x 15 mm and 30 mm x 30 mm).The differences are insignificant and do not influence the safety or efficacy of the device as shown in the performance tests provided in section 9.

The detailed information on INTRAgen's specifications is shown in the following table:

Description			**INTRAgen**
510(K) Number			K142833
Indications for Use			Dermatologic and general surgical procedures for electro coagulation and hemostasis.
Electrosurgical Unit	Major Functions		1. Monopolar 2. Impedance monitor
	Performance Specifications	Output Frequency	6 MHz
		Power Output	KT-07: 5 W - 35 W
			KT-15: 5 W - 136 W
		Tip Energy	KT-07: 10 J - 70 J
			KT-15: 20 J - 136 J
		Fluence	KT-07: 20 – 144 J/cm^2
			KT-15: 2 – 60 J/cm^2
	Physical Specifications		1. Dimensions: 365.0 * 454.8 * 795.5 (mm) 2. Weight: 28 kg

<table>
<tr><td rowspan="5">Active Accessory</td><td colspan="2">Monopolar or Bipolar</td><td>Monopolar</td></tr>
<tr><td rowspan="4">Physical Dimensions and Design</td><td rowspan="2">Dimensions</td><td>KT-07:
31 * 30.4 * 30.3 (mm)
(width * length * height)</td></tr>
<tr><td>KT-15:
31 * 30.4 * 29.4 (mm)
(width * length *height)</td></tr>
<tr><td rowspan="2">Effective Area</td><td>KT-07: 7 * 7 (mm)</td></tr>
<tr><td>KT-15: 15 * 15 (mm)</td></tr>
<tr><td colspan="2">Materials(Patient contact)</td><td>PCB
(polychlorinated biphenyl)
ABS (Acrylonitrile-Butadiene-Styrene Copolymer)</td></tr>
<tr><td>Foot Pedal</td><td colspan="2">Physical Specification</td><td>1) Dimensions: 130 * 150 * 134.6 (mm) (width * length *height)
2) Cable length: 2 (m)
3) Weight: 1 kg</td></tr>
<tr><td colspan="3">Power adjustment increment</td><td><table><tr><th>Level</th><th>Joules (J)</th></tr><tr><td>T</td><td>5</td></tr><tr><td>1</td><td>45</td></tr><tr><td>2</td><td>60</td></tr><tr><td>3</td><td>75</td></tr><tr><td>4</td><td>91</td></tr><tr><td>5</td><td>105</td></tr><tr><td>6</td><td>134</td></tr><tr><td>7</td><td>136</td></tr></table></td></tr>
<tr><td colspan="3" rowspan="4">On/Off Time</td><td rowspan="2">KT-07</td><td>On: 2 sec</td></tr>
<tr><td>Off: 0 sec</td></tr>
<tr><td rowspan="2">KT-15</td><td>On: 1 sec</td></tr>
<tr><td>Off: 0 sec</td></tr>
<tr><td colspan="3">Use or Non-use of Coupling gels</td><td>Use</td></tr>
<tr><td colspan="3">Skin Cooling Methods</td><td>Not use</td></tr>
<tr><td colspan="3">Ointment and/or Drug Product Use</td><td>Not use</td></tr>
</table>

8. Substantial Equivalence

Substantial equivalence to the following predicate devices is claimed:

Description			Proposed [INTRAgen]	Predicate [Thermage ThermaCool System]	Remark
510(K) Number			K142833	K053365	-
Indications for Use			The INTRAgen is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The Thermage ThermaCool System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis".	Same
Electrosurgical Unit	Major Functions		1. Monopolar 2. Impedance monitor	1. Monopolar 2. Impedance monitor 3. Temperature monitor	Performance Testing
	Performance Specifications	Output Frequency	6 MHz	6 MHz	Same
		Power Output	KT-07: 5 W - 35 W KT-15: 5 W - 136 W	330 W	Electrical Safety Testing (IEC 60601-2-2) and Animal Study
		Tip Energy	KT-07: 10 J - 70 J KT-15: 20 J - 136 J	52 J - 220 J	Performance Testing and

					Animal Study
		Fluence	KT-07: 20 – 144 J/cm^2	225 J/cm^2	Performa-nce Testing and Animal Study
			KT-15: 2 – 60 J/cm^2		
	Physical Specifications		1. Dimensions: 365.0 * 454.8 * 795.5 (㎜) 2. Weight: 28 kg	Not known	-
Active Accessory	Monopolar or Bipolar		Monopolar	Monopolar	Same
	Physical Dimensions and Design	Dimensions	KT-07: 31 * 30.4 * 30.3 (mm) (width * length * height)	2.5 * 2.5 (mm), 15 * 15 (mm), 30 * 30 (mm)	Performa-nce Testing
			KT-15: 31 * 30.4 * 29.4 (mm) (width * length * height)		
		Effective Area	KT-07: 7 * 7 (mm)	15 * 15 (mm), 2.5 * 2.5 (mm), 30 * 30 (mm)	
			KT-15: 15 * 15 (mm)		
	Materials(Patient contact)		PCB (polychlorinated biphenyl) ABS (Acrylonitrile-Butadiene-Styrene Copolymer)	Polymid film	Biocompa-tibility Testing
Foot Pedal	Physical Specification		1) Dimensions: 130 * 150 * 134.6 (mm) (width * length * height) 2) Cable length: 2 (m) 3) Weight: 1 kg	Not known	-

<table>
<tr>
<td>Power adjustment increment</td>
<td>
<table>
<tr><th>Level</th><th>Joules (J)</th></tr>
<tr><td>T</td><td>5</td></tr>
<tr><td>1</td><td>45</td></tr>
<tr><td>2</td><td>60</td></tr>
<tr><td>3</td><td>75</td></tr>
<tr><td>4</td><td>91</td></tr>
<tr><td>5</td><td>105</td></tr>
<tr><td>6</td><td>134</td></tr>
<tr><td>7</td><td>136</td></tr>
</table>
</td>
<td>
<table>
<tr><th>Level</th><th>Joules (J)</th></tr>
<tr><td>10.5</td><td>52</td></tr>
<tr><td>11.0</td><td>58</td></tr>
<tr><td>11.5</td><td>65</td></tr>
<tr><td>12.0</td><td>72</td></tr>
<tr><td>12.5</td><td>79</td></tr>
<tr><td>13.0</td><td>87</td></tr>
<tr><td>13.5</td><td>95</td></tr>
<tr><td>14.0</td><td>103</td></tr>
<tr><td>14.5</td><td>112</td></tr>
<tr><td>15.0</td><td>121</td></tr>
<tr><td>15.5</td><td>131</td></tr>
<tr><td>16.0</td><td>140</td></tr>
<tr><td>16.5</td><td>151</td></tr>
<tr><td>17.0</td><td>161</td></tr>
<tr><td>17.5</td><td>172</td></tr>
<tr><td>18.0</td><td>184</td></tr>
<tr><td>18.5</td><td>195</td></tr>
<tr><td>19.0</td><td>207</td></tr>
<tr><td>19.5</td><td>220</td></tr>
</table>
</td>
<td>Performa-nce Testing and Animal Study</td>
</tr>
<tr>
<td>On/Off Time</td>
<td>KT-07
On: 2 sec
Off: 0 sec
KT-15
On: 1 sec
Off: 0 sec</td>
<td>Not Known</td>
<td>Performa-nce Testing and Animal Study</td>
</tr>
<tr>
<td>Use or Non-use of Coupling gels</td>
<td>Use</td>
<td>Use</td>
<td>Same</td>
</tr>
<tr>
<td>Skin Cooling Methods</td>
<td>Not use</td>
<td>Uses a bio-safe cryogen Tetrafluoroethane</td>
<td>Performa-nce Testing</td>
</tr>
<tr>
<td>Ointment and/or Drug Product Use</td>
<td>Not use</td>
<td>Not known</td>
<td></td>
</tr>
</table>

The indications for use and technological characteristics of the INTRAgen device are substantially equivalent to theThermageThermaCool System. The key technological characteristics of the INTRAgen, such as energy type and operating principle, are equivalent to the predicate device.The design and components in the INTRAgen device, including the RF generator and the hand piece applicator are also similar to the design and components found in the predicate ThermageThermaCool System.

The major differences between the subject device and the predicate device are power output, tip energy and electrode size from the predicate device. However, the pre-clinical study using the porcine model demonstrated the subject device would perform as well as the predicate devices in the market. The INTRAgen device also underwent performance testing, including software validation testing (provided in Section 4) and electrical and mechanical safety testing according to IEC 60601-1 and

electromagnetic compatibility testing according to IEC 60601-1-2 (provided in Section 10) and bench tests (provided in Section 9).These performance tests demonstrated that the differences in the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the INTRAgen is substantially equivalent to the predicate ThermageThermaCool System, cleared under 510(k) K053365.

9. Summary of Non-Clinical Performance Data

- Electrical Safety and Electromagnetic Compatibility

The tests were performed on the INTRAgen to confirm electrical safety and electromagnetic compatibility in accordance with IEC 60601-1, IEC 60601-2-2, and IEC 60601-1-2. The results were acceptable.

- Biocompatibility

The patient contacting part of the INTRAgen is the active electrode and it is made of PCB (Polychlorinated Biphenyl) and ABS (Acrylonitrile-Butadiene-Styrene Copolymer). Biocompatibility test has been conducted according to the ISO 10993-1 standards, and the test results support that it is biocompatible.

- Bench Data

Bench tests were performed to evaluate the dimensional accuracy, the accuracy of measurement for impedance, the accuracy of the active electrode output and output waveform. The test results were acceptable.
An additional bench test was performed to demonstrate that the temperature of the skin surface does not go up to the point where it can cause damage to the skin tissue even when the cooling system is not used. The results demonstrated that the temperature of the skin surface did not go up to the point where it could cause damage to the skin tissue.

- Pre-Clinical

A pre-clinical trial was performed to evaluate performance of the subject device. The test was performed on a porcine tissue model using different joule energy levels and active electrodes.

- Study purpose: The study was designed to evaluate the effects of the novel grid fractional RF treatment on skin structure and collagen in vivo.

- Follow up periods/days: The wound healing response was evaluated histologically and by RT-PCR up to 10 weeks post-RF treatment.
- Animal type: Porcine
- Treatment applied: The INTRAgen RF device was used to deliver RF energy to skin.
- Histology evaluation: The study results showed that vigorous wound healing response was initiated post-treatment with progressive increase in inflammatory cell infiltration from day 2 through 10 weeks. Furthermore, through both immune histochemical and PCR studies, it was found that profound neocollagenesis and neoelastogenesis following RF treatment of micropigskin occurred.

In conclusion, the test results of the pre-clinical study demonstrated that the subject device is substantially equivalent to the predicate device.

- Sterilization

The active electrodes (KT-07 and KT-15) are sterilized in its final packaging using 20% Ethylene Oxide (EtO) and 80% CO2. The EtO sterilization process has been validated in accordance with ISO 11135-1:2007.

▪ INTRAgen complies with the following recognized standards. The following table lists the non-clinical testing performed.

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 INTRAgen met all The acceptance criteria in accordance with IEC 60601 1:2009, IEC 60601-2-2:2009 and IEC 60601-1-2:2007.
Biocompatibility Testing	• Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Pyrogen	The active electrodes are biocompatible.
Performance Testing	• Dimensional Inspection • Accuracy of Measurement • Energy Output • Current Density • On/off time • Output Waveform • Skin Temperature	The INTRAgen met all the acceptance criteria.

Pre-clinical Trial	• Tissue Analysis • Total RNA isolation and real-time RT-PCR • Statistical analysis	The test results demonstrated that the subject device is substantially equivalent to the predicate device.
Sterilization	• ISO 11135-1:2007	The INTRAgen met all the acceptance criteria in accordance with ISO 11135-1:2007.

10. Summary of Clinical Test

No clinical studies were considered necessary and performed.

11. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR part 807, FDA's "Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery" and based on the information provided in this premarket notification, Jeisys Medical Inc. concludes that INTRAgen is safe, effective and substantially equivalent to predicate devices for dermatologic and general surgical procedures for electrocoagulation and hemostasis.