



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

October 27, 2016

Jeisys Medical Inc.  
% Kathy Maynor  
Consultant  
Ronyam Enterprises LLC  
26 Rebecca Ct  
Homosassa, Florida 34446

Re: K162169

Trade/Device Name: EdgeOne CO2 Laser

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And  
In Dermatology

Regulatory Class: Class II

Product Code: GEX, ONG

Dated: July 30, 2016

Received: August 3, 2016

Dear Ms. Maynor:

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" (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 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,

Jennifer R. Stevenson -

A

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)

K162169

Device Name

Jeisys EdgeOne CO2 Laser

Indications for Use (Describe)

It is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology(ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

## Section 8 – 510(k) Summary or 510(k) Statement

### I. General Information

Submitter: JEISYS MEDICAL INC.  
307 Daeryung Techno Town 8th  
481-11, Gasan-Dong, Geumcheon-Gu  
Seoul Seoul Teugbyeolsi, KOREA, REPUBLIC  
OF 153-775

Contact Person: Kathy Maynor  
Consultant  
352-586-3113 (cell)

Summary Preparation Date: July 29, 2016

### II. Names

Device Names: The Jeisys EdgeOne CO2 Laser

Primary Classification Names: Surgical Powered Light Instrument,

### III. Predicate Devices

K #	Predicate Device
K100590	EDGE CO2 LASER SYSTEM
K133895	DEKA SMARTXIDE LASER SYSTEM

### IV. Product Description

The Jeisys EdgeOne CO2 Laser is comprised of the following major components:

1. The main console unit
2. Delivery handpieces (2 surgical and one fractional)
3. Footswitch.
4. Accessories

### V. Indications for Use

It is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology(ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery

(including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

## VI. Summary of Technical Characteristics

**Table 1: Salient Characteristics of the Jeisys EdgeOne CO2 Laser and the Predicate Devices**

<b>Parameter</b>	<b>K16XXX Jeisys Edge One Laser</b>	<b>K100590 Jeisys Edge One Laser (Predicate Device)</b>	<b>K133895 Deka Smartxide 2 (Secondary Predicate)</b>
Product Code & Regulation No.	<b>GEX, ONG 21 CFR 878.4810</b>	<b>GEX 21 CFR 878.4810</b>	<b>GEX 21 CFR 878.4810</b>
Laser Type	CO2	CO2	CO2
Laser wavelength	10.6µm	10.6µm	10.6µm
Output power	30W	30W	60W
Pulse Duration	1-1000ms	1-1000ms	100 ~2,000 µs
Fractional Pulse energy	1-300mJ	1-300mJ	Unknown
Repetition rate	10-500Hz	10-500Hz	5Hz to 100Hz
Scan area	15 x 15mm <sup>2</sup>	15 x 15mm <sup>2</sup>	15 x 15mm
Spot size (fractional)	120um, 350um, 800um	120um, 350um, 800um	125µm, 155µm, 267µm, 325µm, 489µm, 530µm
Surgical handpieces	0.15, 1	NA	0.15, 1, collimated, dental
Operational mode	Fractional mode, normal mode (CW, Pulse, Single Pulse, Repeat, Group pulse, Ultra)	Fractional mode, normal mode (CW, Pulse, Single Pulse, Repeat, Group pulse, Ultra)	Fractional CW, SP, DP, HP, UP Normal Interlaced SmartTrack
Aiming beam	Diode laser(Red) 655 +/- 10nm, Max 1mW	Diode laser(Red) 655 +/- 10nm, Max 1mW	Diode laser (Red) 635nm, 4mW max
Fractional	Spot density 0-42.4%	Spot density 0-42.4%	Unknown
Cooling	Water	Water	Water
User Interface	LCD touch screen	LCD touch screen	LCD touch screen
Optical guide	Articulated arm	Articulated arm	Articulated arm

Electrical Requirements	230V~, 50/60Hz, 500VA(max. laser output), 100 VA(stand-by)	230V~, 50/60Hz, 500VA(max. laser output), 100 VA(stand-by)	100-120V~/220-230V~, 50/60Hz, 1600VA
Indications for Use	It is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology(ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.	The Edge CO 2 laser when used in traditional non-fractionated scanner mode is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues. The Edge CO 2 laser when used in fractionated mode is indicated for ablative skin resurfacing.	It is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology(ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

## VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Jeisys EdgeOne CO2 laser is substantially equivalent to the predicate devices.

Product testing performed included:

IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007) Medical electrical equipment – General Requirements for Electrical Safety - NO DEVIATIONS

IEC 60601-2-22:2007 (Third Edition) + A1 (2012) for use with IEC 60601-1:2005 + A1 (2012) Medical Electrical Equipment - Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC60601-1-2:2007 - Section 6, not life-supporting equipment, group 1&2, Class A – Medical Electrical Equipment PART 1: GENERAL REQUIREMENTS FOR SAFETY 2. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS

## **VIII. Conclusion**

The Jeisys EdgeOne CO2 laser was found to be substantially equivalent to the predicate devices.

The Jeisys EdgeOne CO2 laser shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate devices.