July 15, 2020

Shanghai Apolo Medical Technology Co., Ltd.
℅ Shelley Li
Director
Shanghai Landlink Medical Information Technology Co., Ltd.
Room 703, 705, Building 1, West Guangzhong Road 555
Jingan District, Shanghai, Shanghai 200071, China

Re: K201109
Trade/Device Name: CO2 Laser Therapy System
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
Dated: April 16, 2020
Received: April 27, 2020

Dear Shelley Li:

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,

Colin Kejing Chen
Acting 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)*
K201109

Device Name
CO2 Laser Therapy System

Indications for Use *(Describe)*
The CO2 Laser Therapy System is used for body soft tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology.

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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K201109-510(k) summary

I Submitter

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Preparation date: 2020-07-09

II Proposed Device

Trade Name of Device:	CO_2 Laser Therapy System
Common name:	Powered Laser Surgical Instrument
Regulation Number:	21 CFR 878.4810
Regulatory Class:	Class II
Product code:	GEX
Review Panel	General & Plastic Surgery

III Predicate Devices

a

510(k) Number:	K162169
Trade name:	EdgeOne CO_2 Laser
Common name:	Powered Laser Surgical Instrument
Classification:	Class II
Product Code:	GEX
Manufacturer	Jeisys Medical Inc.

b

510(k) Number:	K133895
Trade name:	DEKA SmartXide^2 Laser System
Common name:	Powered Laser Surgical Instrument
Classification:	Class II
Product Code:	GEX
Manufacturer	Electronic Engineering S.p.A.

IV Device description

The CO_2 Laser Therapy Systems generate a 10,600nm wavelength, which is absorbed by water in the tissue. The laser energy heats up the water until it reaches a boiling point causing the evaporation of the affected tissue. Some heat is absorbed by tissue adjacent to the ablated target area, causing tissue coagulation which induces hemostasis (the cessation of bleeding) as well as thermal stimulation of deep skin layers, which induces fibroblast stimulation and neocollagenesis (the formation of new collagen).

V Indication for use

The CO_2 Laser Therapy System is used for body soft tissue vaporization and coagulation in dermatology and plastic surgery, general surgery, gynecology.

VI Comparison of technological characteristics with the predicate devices

Item	Proposed device	Predicate device (K162169)	Predicate device (K133895)
Product name	CO_2 Laser Therapy System	EdgeOne CO_2 Laser	DEKA SmartXide^2 Laser System
Product Code	GEX	GEX	GEX
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Class	Class II	Class II	Class II
Indication for use	The CO_2 Laser Therapy System is used for body soft tissue vaporization and coagulation in dermatology and plastic surgery, general surgery, gynecology.	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	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

			endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indication for ablative skin resurfacing.	surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indication for ablative skin resurfacing.
Laser Type	RF Sealed-off CO_2		CO_2	CO_2
Light Delivery system	Articulated arm		Articulated arm	Articulated arm
CO_2 Laser wavelength	10600nm		10600nm	10600nm
Aiming beam wavelength	< 2mw /650nm /Semiconductor Laser LD		Diode laser(Red) 655 +/- 10nm, Max 1mW	Diode laser (Red) 635nm, 4mW max
Laser Controls	Footswitch		Footswitch	Footswitch
Output power	HS-411: 1~35W HS-411A: 1~55W		30W	60W
Pulse energy	1~300mJ/dot		1-300mJ	Unkown
Pulse duration	CW	-	1-1000ms	1-2000us
	Single	10~500ms		
	Pulse	On time: 5~500ms Off time: 1-500ms		
	S. Pulse	On time: 1~4ms Off time: 1-100ms		

	U pulse	On time: 0.1~0.9ms Off time: 1-100ms		
Spot size	150um （fractional）		120um, 350um, 800um	125μm, 155μm, 267μm, 325μm, 489μm, 530μm
Scan area size	2x2mm~20x20mm		15mmx15mm	15mmx15mm
Operational mode	Fractional mode, normal mode and vaginal (CW, Single, Pulse, S. pulse, U. pulse)		Fractional mode, normal mode (CW, Pulse, Single Pulse, Repeat, Group pulse, Ultra)	Fractional CW, SP, DP, HP, UP Normal Interlaced SmartTrack
User interface	LCD color Touchscreen		LCD color Touchscreen	LCD color Touchscreen
Laser classification	Class IV		Class IV	Class IV
Software	Yes		Yes	Yes

VII Non-Clinical Testing

A battery of tests have been performed to verity that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:

Electrical safety and electromagnetic compatibility

IEC 60601-1: 2005+corr.1:2006+Corr.2.2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements

IEC 60601-2-22:2007(third edition)+A1:2012 for use in conjunction with IEC

60601-1:2005 (third edition)+A1:2012 Medical electrical equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

VIII Clinical Testing

It is not applicable.

Ⅸ Conclusion

Base on the performance testing and validation studies that the subject device is substantially equivalent to the predicate device.