I-tech Industries Srl
℅ Jay Mansour
Principal
Mansour Consulting LLC
845 Aronson Lake Court
Roswell, Georgia 30075

January 11, 2019

Re: K182453
Trade/Device Name: ICOONE h (also referred to as ICOONE LASER and ICOONE -h 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: NUV
Dated: December 7, 2018
Received: December 12, 2018

Dear Jay Mansour:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.01.11 12:08:58 -05'00'

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)*
K182453

Device Name
ICOONE h (also referred to as ICOONE LASER and ICOONE –h LASER)

Indications for Use *(Describe)*

ICOONE h is indicated for the relief of minor muscle aches and pain, relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

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.

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510k Summary

As required by 21 CFR 807.92 (c)

1- Date summary prepared: 1/11/2019

2- Owner/Submitter/Sponsor/Applicant information:

I-Tech Industries S.r.l
Via Cicogna 34/B 40068
San Lazzaro Di Savena
Bologna
Italy

3- Device information:

Common/usual/classification name: Massager, Vacuum, Light Induced Heating

Device name: ICOONE h (also referred to as ICOONE LASER and ICOONE –h LASER)

FDA 3 letter code	NUV
FDA regulation number: 21 CFR	878.4810
Regulation medical specialty	General & Plastic Surgery
Review panel	General & Plastic Surgery Division of Surgical Devices (DSD) General Surgery Devices Branch One - Light Based/Laser (GSDB1)
Class	II

4- Substantial equivalency is claimed against the following predicate device(s):

510k number	Trade or Proprietary or Model Name	Manufacturer	Primary predicate?
K053611	SmoothShapes	Biocellulase, Inc.	No
K061603	SmoothShapes	Biocellulase, Inc.	Yes

5- Description of the device:

The Icoone-h device is Therapeutic Massager machine attached to pivoting wheels, connected to a rolling stand, with a series of hand pieces equipped with motorized rollers, which are the core of the technology and that, opportunely guided by an operator, are applied to the patient's body.

Icoone-h Laser is also equipped with two light sources inside the Robosolo hand piece, each with the following wave lengths:

LED @ 650nm (50Mw)
Laser @ 915nm (1W)

The light sources can be activated through the display, either combined or independently (only one of the two or both).

The sources are neither adjustable in intensity (always output at nominal value, as per specifications) nor in frequency (always continuous - CW).

Once selected, by turning on the Robosolo hand piece, both suctioning and light emission are activated at the same time.

The light is emitted via laser diodes or LEDs controlled by a dedicated power driver.

6- Intended use + indications for use

ICOONE h is indicated for the relief of minor muscle aches and pain, relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

7- Basis for a determination of substantial equivalency:

(a) Indications for use:

The indication for use is identical to the predicates'.

(b) Technological characteristics:

The technological characteristics are substantially equivalent to the predicate device, meeting the same technical standards.

Device name	**Icoone -h**	**Biocellulase Smoothshapes**	**Biocellulase Smoothshapes**	**Substantial equivalency: same or different**
510(k) number	TBD	K053611	K061603	
System component	Laser, Massage, Suction, Rollers	Laser, Massage, Suction, Rollers	Laser, Massage, Suction, Rollers	Same
Mechanical massage	yes	yes	yes	Same
Weight	191.80 lb (87 kg)	59.52 lb (27 kg)	101.41 lb (46 kg)	Different (but similar)
Dimension	37.40x80.71x19.68 inch (95x205x50 cm)	31.47x19.68x13.78 inch (80x50x35 cm)	21.26x23.23x51.97 inch (54x59x132 cm)	Different (but similar)
Light emitting safety	IEC 60825-1: 2007 (in conjunction with IEC 60601-1: 2005) IEC 60601-2-22: 2007	21 CFR 1040	21 CFR 1040	Same (FDA accepts the equivalency)
Electrical Safety	CEI EN 60601-1:2007 /A11: 2012	IEC/EN 60601-1-1: 1995 IEC/EN 60601-1-1: 1995	IEC/EN 60601-1-1: 1995 IEC/EN 60601-1-1: 1995	Same (our device is not a system and IEC 60601-1-1 is not applicable)
EMC	CEI EN 60601-1-2: 2010	IEC 60601-1-2:1993, 2001	IEC 60601-1-2:1993, 2001	Same
Patient contact material	Handpiece suction rollers	Handpiece suction rollers	Handpiece suction rollers	Same
Biocompatibility	Cytotoxicity, irritation, Sensitization	unknown	unknown	(As per requirements)
Indication for use	Relieves of minor muscle aches and pains, Relieves muscle spasms, Temporary improves local blood circulation, Temporary reduces in appearance of cellulite	Relieves of minor muscle aches and pains, Relieves muscle spasms, Temporary improves local blood circulation, Temporary reduces in appearance of cellulite	Relieves of minor muscle aches and pains, Relieves muscle spasms, Temporary improves local blood circulation, Temporary reduces in appearance of cellulite	Same

Power Source	240/110 Vac	240/110 Vac	240/110 Vac	Same
IR power	max 1W	max 1W / 915nm max 0.5 W / 650 nm	max 15W / 915 nm max 1W / 650 nm	Different: Similar to K053611 Safer than K061603
Infrared wavelengths	650nm (LED) 915 nm (LASER)	640 nm - 660 nm (LED) 880 nm - 940 nm (LASER)	650nm (LED) 915 nm (LASER)	Same
Max. IR output energy density	26.9 W/m2	unknown	unknown	(safe and effective)
Vacuum	Fractioned	Pulsed	Pulsed	Different (but similar)
Treated area	3.15x2.36 inch (80x60mm - Robosolo head) 2.36x1.97 inch (60x50mm - Robotwin head) x2 1.97x1.38 inch (50x35mm - Robomini head) 0.031x0.031 inch (0.8x0.8 mm - Robomicro head with applicator "D") 0.027x0.91 inch (0.7x23 mm - Robomicro head with applicator "C") 0.59x1.14 inch (15x29 mm - Robomicro head with applicator "B")	1.57x1.57 inch (40x40mm)	unknown	Different (but similar)

(c) Non-clinical tests- brief discussion:

The standards that we comply with (listed above) confirm the safety, fit and effectiveness.

(d) Clinical tests- brief discussion:

Not applicable.

(e) Non-clinical and clinical tests- conclusions drawn demonstrating that the device is as safe and as effective, and performs as well as or better than the predicate device(s):

ICOONE h performs as designed, in accordance with requirements. It is as safe and effective as the predicate device(s).