June 22, 2021

I-Tech Industries SRL
% Jay Mansour
Principal
Mansour Consulting LLC
845 Aronson Lake Court
Roswell, Georgia 30075

Re: K211272
Trade/Device Name: ICOONE Laser Med (also referred to as ICOONE Medical 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, ISA
Dated: April 12, 2021
Received: April 27, 2021

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 and Part 809); 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,

Purva Pandya
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K211272

Device Name
ICOONE Laser med (also referred to as ICOONE Medical laser)

Indications for Use *(Describe)*

ICOONE Laser med (also referred to as ICOONE Medical laser) 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.

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510K # K211272

510(k) #K211272

510k Summary:

As required by 21 CFR 807.92 (c)

1 - Date Summary Prepared: June 8, 2021

2 - Owner/Submitter/Sponsor/Applicant information:

APPLICATION CORRESPONDENT
Jay Mansour, MSQA, BE, RAC
Principal
Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA

OWNER/SUBMITTER/SPONSOR/APPLICANT
Gianfranco Tudico, CEO
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Via Casalino 5/H
Bergamo
Italy 24121

3 - Device Information:

Common/usual name: massager, vacuum, light induced heating

Device name:

	Device Model Name	Model Number
1	ICOONE Laser Med (also called ICOONE MEDICAL LASER)	650EC24

FDA 3 Letter Code	NUV	ISA
FDA regulation number: 21 CFR	878.4810	890.5660
Classification name	Laser Surgical instrument for use in General and Plastic Surgery and in Dermatology	Therapeutic massager
Review panel	General & Plastic Surgery	Physical Medicine
Class	2	1

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

510k Number	Trade or Proprietary or Model Name	Manufacturer	Primary Predicate?
K182453	ICOONE h (also referred to as ICOONE LASER and ICOONE -h LASER)	I-tech Industries Srl	Yes

5 - Description of the device

Icoone Medical Laser (also referred to as Icoone Lase med) 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.

The combined synergistic action between the micro-stimulators (rollers) and a negative pressure (vacuum) created within the hand pieces grasp the skin tissues allowing to achieve the same effects of kneading and stroking tissue by hand. Applications are pre-set by the machine or the operator in relation to intensity, frequency, length of session, degree of tissue suctioning, and allow to address the issues of each individual in an absolutely targeted manner.

Icoone Medical Laser (model ref 650EC24) (also referred to as Icoone Laser med) is also equipped with two light sources inside the Robosolo hand piece, each with the following wave lengths: - Led @ 650nm (50mW) - Laser @ 915nm (1W)

Through the display, the light sources can be fully deactivated, or both activated, or only LED activated.

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 - Indications for use

ICOONE Laser med (also referred to as ICOONE Medical laser) 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 – Comparison with predicate device:

(a) Indications for use: the indication for use is identical to the predicates.

(b) Technological characteristics: the technological characteristics are the same or similar to the predicate device, meeting the same technical standards.

Company name	ICOONE Laser med (also referred to as ICOONE Medical laser)	ICOONE h (also referred to as ICOONE LASER and ICOONE -h LASER)	Comparison: same or different
Premarket Notification 510k	K211272	K182453	
System component	Laser, Massage, Suction, Rollers	Laser, Massage, Suction, Rollers	same
Mechanical massage	yes	yes	same
Weight	191,80 lb (87 kg)	191,80 lb (87 kg)	same
Dimension	37,40x80,71x19,68 inch (95x205x50 cm)	27,56x72,84x19,68 inch (70x185x50 cm)	same
Electrical Safety	Medical electrical equipment - Part 1-2: General requirements for safety - According to CEI EN 60601-1: 2006 / A11: 2011 / A1: 2013/A2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests - According to CEI EN 60601-1:2007 /A11:2012 CEI EN 60601-1-2:2010	same
EMC	Medical electrical equipment - Part 1-2: General requirements for Electromagnetic disturbances - Requirements and tests - According to CEI EN 60601-1-2: 2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests - According to CEI EN 60601-1:2007 /A11:2012 CEI EN 60601-1-2:2010	same
Patient contact material	Handpiece suction rollers	Handpiece suction rollers	same
Biocompatibility	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization / Biological Evaluation Of Medical Device – Part 5: Test for cytotoxicity - According to ISO10993-10:2010, 10993-5:2009 and 10993-12:2012	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization / Biological Evaluation Of Medical Device – Part 5: Test for cytotoxicity - According to ISO10993-10:2010, 10993-5:2009 and 10993-12:2012	same
Indication for use	ICOONE Laser med (also referred to as ICOONE Medical laser) 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.	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.	same
Power Source	240/110 Vac	240/110 Vac	same
IR power	LASER 915 nm max 1W	LASER 915 nm max 1W	same
Infrared wavelengths	650nm (LED) / 915 nm (LASER)	650nm (LED) / 915 nm (LASER)	same
Max. IR output energy density	2.69 W/m2	2.69 W/m2	same
Vacuum	Fractioned	Fractioned	same
Treated area	3,15x2,36 inch (80x60mm - Robosolo head) 2,36x1,97 inch (60x50mm - Robotwin head) x2 1,97x1,38 inch (50x35mm - Robomini head) x2 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") 1,02x1,57 inch (26x40mm - Robomicro head with applicator 26mm) 0,78x1,26 inch (20x32mm - Robomicro head with applicator 20mm) 0,43x0,31 inch (11x8mm - Robomicro head with applicator 13,8mm)	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")	same (applicators added)

8- Performance Data:

Electrical safety and electromagnetic compatibility (EMC) testing:

- EN 60601-1:2006/A11: 2011/A1: 2013/A2: 2014, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

  Note: Gap testing was provided demonstrating conformance of the subject device to the FDA-recognized standard for electrical safety (AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012)

- EN 60601-1-2:2015, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Electromagnetic Compatibility

Software Verification and Validation Testing:

- Software verification and validation testing were conducted and documentation was provided as recommended per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Additional non-clinical testing:

- IEC 60601-2-22 (Edition 3.1 2012-10), Medical Electrical Equipment - Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

- IEC 60825-1 (Edition 2.0 2007-03), Safety of Laser Products - Part 1: Equipment classification and requirements.

9- Conclusions:

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.