September 22, 2023

B&M S.R.L. Marketing Nel Benessere
% Chiara Violini
Consultant
Endo Engineering Srl
Via Del Consorzio, 41
Falconara Marittima, Ancona 60015
Italy

Re: K231092
Trade/Device Name: T-shape 2
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, PBX
Dated: August 22, 2023
Received: August 23, 2023

Dear Chiara Violini:

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,

Tanisha L. Hithe -S

Tanisha L. Hithe -S
2023.09.22
20:49:01 -04'00'

Tanisha Hithe, MS, MHS
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231092

Device Name
T-SHAPE 2

Indications for Use *(Describe)*
The T-SHAPE 2 and its hand pieces are indicated for the relief of minor muscle aches and pains, relief of muscle spasm, 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.

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510(k) Summary K231092

Introduction:

This document contains the 510(k) Summary for the T-SHAPE 2 device.
The content of this summary is based on the requirements of 21 CFR 807.92(c).

Applicant/ Manufacturer Name and Address:	B&M S.R.L. MARKETING NEL BENESSERE Via Leonardo Bruni, 25 20158 Milano (MI) Italy
510(k) Contact Person:	Chiara Violini Consultant Email: c.violini@endoengineering.it Phone: +39-071-9156048 Fax: +39-071-0971883
Date Prepared:	30/01/2023
Device Name:	T-SHAPE 2
Common or Usual Name:	Multifunction platform with LLLT, RF, vacuum and massager.
Classification:	Class II
Classification Name:	Massager, Vacuum, Light Induced Heating (NUV) Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Regulation number:	21 CFR 878.4810 (NUV) 21 CFR 878.4400 (PBX)
Classification product code:	NUV, PBX
Predicate Devices:	K122579 - VelaShape – Syneron Medical, Limited K191528 – Venus Legacy Pro – Venus Concept Ltd. K211272 – ICOONE Laser Med – I-Tech Industries SRL

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Description of the device:

T-SHAPE 2 treatment is based on the simultaneous application of heat and mechanical manipulation to the tissue, wherein the heat is derived from light energy at a controlled infrared wavelength and from conducted radio frequency (RF) energy and the mechanical manipulation is derived from massage and/or vacuum.

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 targeted manner.

T-SHAPE 2 is also equipped with:

- Two light sources type inside some handpieces (see below) with the following wavelengths: - 650 and 980 nm.
- Electrodes for bipolar RF energy (500 kHz/ 1 MHz / 1,5 MHz).

Through the display, the light sources and RF energy can be fully deactivated or activated.

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

For the RF energy the user can select frequency between 2 MHz, 1,5 MHz, 1 MHz, 500 kHz and intensity between the 10 levels available.

T-SHAPE 2 comprises a main console unit and several handpieces.

A microprocessor-based system controller is used to monitor and direct all the system function and the graphic user interface.

The main console can be connected to the following handpieces (two different hand piece can be connected at the same time):

- Large multipole handpiece with 6 diode laser and 6 RF plates;
- Medium multipole handpiece with 4 diode laser and 4 RF plates;
- Small multipole handpiece 4 RF plates and 1 red LED;
- Thermal imaging camera;
- Roll handpiece with 4 diode laser and 2 motorized roller with RF;
- Mesosphere handpiece with 45 motorized rotating spheres.

Indication for Use:

The T-SHAPE 2 and its hand pieces are 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.

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Comparison of Technological Characteristics:

T-SHAPE 2 has the same technological characteristics (massager, vacuum, RF energy, light source, control mechanisms) and specifications as its predicate devices.

BALDAN GROUP	**T-SHAPE 2**	B&M S.R.L. MARKETING NEL BENESSERE Via Leonardo Bruni, 25 20158 Milano (MI) Phone: (+39) 02 393 5831 Email: info@baldangroup.it

Specifications	Predicate Device (Primary)	Predicate Device	Predicate Device	Device object of 510(k)	Comparison to Predicate
Device Name (K number)	**VelaShape K122579**	**Venus Legacy Pro K191528 with 4D Body (LB2) and 4D Face (LF2) applicators**	**ICOONE Laser Med K211272**	**T-SHAPE 2**	/
Submitter	Syneron Medical, Limited	Venus Concept Ltd.	I-Tech Industries SRL	B&M S.R.L. MARKETING NEL BENESSERE	/
Product Code	NUV	GEX, PBX	NUV, ISA	NUV, PBX	Not considered ISA and GEX because they are already considered in NUV and PBX
Regulation Number	21 CFR 878.4810	21 CFR 878.4400	21 CFR 878.4810	21 CFR 878.4810	/
Regulatory Class	II	II	II	II	/
Product Picture					/

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Specifications	Predicate Device (Primary)	Predicate Device	Predicate Device	Device object of 510(k)	Comparison to Predicate
Device Name (K number)	**VelaShape K122579**	**Venus Legacy Pro K191528 with 4D Body (LB2) and 4D Face (LF2) applicators**	**ICOONE Laser Med K211272**	**T-SHAPE 2**	/
Mains	110 VAC; 4A; 50 Hz; Single Phase 230 VAC; 2.5A; 50 Hz; Single Phase	100-120 VAC / 60Hz 220-240 VAC / 50Hz	240/110 Vac	100-120 VAC / 60Hz 220-240 VAC / 50Hz	Equivalent to Predicate Devices
Weight	20 kg. / 44.1 lbs	40 kg	191,80 lb (87 kg)	95 kg	Equivalent to Predicate Devices
Dimensions	38 x 49 x 132 cm / 15 x 19 x 51.8 inche	40X40X100 cm (DxWxH)	37,40x80,71x19,68 inch (95x205x50 cm)	57 x 86 x 1.70 cm	Equivalent to Predicate Devices
Biocompatibility	Unknown	Materials are biocompatible	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 for cytotoxicity, irritation, and skin Sensitization	Equivalent to Predicate Devices

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Specifications	Predicate Device (Primary)	Predicate Device	Predicate Device	Device object of 510(k)	Comparison to Predicate
Device Name (K number)	**VelaShape K122579**	**Venus Legacy Pro K191528 with 4D Body (LB2) and 4D Face (LF2) applicators**	**ICOONE Laser Med K211272**	**T-SHAPE 2**	/
Indications for use	The VelaShape is indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences.	When used with the 4D Body (LB2) and 4D Face (LF2) applicators, the Venus Legacy Pro device is intended for the delivery of non-thermal RF combined with Massage and magnetic field pulses for the treatment of the following medical conditions: • Relief of minor muscles aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite	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.	The T-SHAPE 2 and its hand pieces are 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.	Equivalent to Predicate Devices
System component	Light, RF, Massage, Suction, Rollers	RF, Massage, Suction, Rollers	Light, Massage, Suction, Rollers	Light, RF, Massage, Suction, Rollers	Equivalent to primary predicate device
Massage					

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Specifications	Predicate Device (Primary)	Predicate Device	Predicate Device	Device object of 510(k)	Comparison to Predicate
Device Name (K number)	**VelaShape K122579**	**Venus Legacy Pro K191528 with 4D Body (LB2) and 4D Face (LF2) applicators**	**ICOONE Laser Med K211272**	**T-SHAPE 2**	/
Mechanical Massage	Yes	Yes	Yes	Yes	Equivalent to Predicate Devices
Light					
Infrared wavelengths	850 nm	Not present	650nm (LED)/ 915 nm (LASER)	650/980 nm	See Substantial Equivalence discussion
Maximum power/power density	3.3 W	/	1 W (915 nm) 2.69 W/m^2	2 W/m^2	
Suction/vacuum					
Mode	Pulsed	Unknown	Fractioned	Pulsed	Equivalent to predicate devices
Maximum Pressure	– 390 mbar	- 400 mbar	Unknown	- 400 mbar	Equivalent to predicate devices
Radio Frequency					
Frequency	1 MHz	1 MHz	Not present	Selectable between 2 MHz 1,5 MHz 1 MHz 500 kHz	See Substantial Equivalence discussion
Peak RF POWER	150 W	150 W	/	150 W	Equivalent to predicate devices
Mode	Bi-polar	Bi-polar	/	Bi-polar	Equivalent to predicate devices

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Performance data:

The following performance data are provided in support of the substantial equivalence determination:

Biocompatibility testing

Materials in contact with patient skin, for a duration less than 24 hours, were evaluated according to the "biocompatibility flow chart for the selection of toxicity tests for 510(k)s", attachment C of "Criteria of Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (blue book memo)".

Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the T-SHAPE 2 device.

The system complies with the IEC 60601-1, IEC 60825-1 standards for safety and the IEC 60601-1-2 and IEC TR 60601-4-2 standards for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Performance Bench Testing

T-SHAPE 2 has been evaluated to verify the skin tolerance, effect and cosmetic properties of a professional treatment through evaluations and instrumental analysis performed by professionals under medical supervision and consumer self-assessments.

Comparison of Intended Use:

T-SHAPE 2 device's Intended Use is the same Intended Use of its predicate device.

Substantial Equivalence:

T-SHAPE 2 device is as safe and effective as its predicate devices.

T-SHAPE 2 device has the same intended use and same technological characteristics and specification as its predicate devices, moreover, T-SHAPE 2 has been tested in accordance to consensus standard to demonstrate safety and Performance.

The choice of four frequencies allows you to act more precisely on different layers of the tissue, contrary to a single fixed frequency.

The safety of the treatment is due to the characteristics of the latest generation equipment, which allow you to constantly monitor the parameters set during the session. The system has two safety levels: the first is preset on the skin resistance values with gradual emission of current pulses, the skin resistance have been considered variable between 50 and 500 Ohm and the voltage and power values of the settable 10 level has been calculated considering this range of skin resistance; the second is the regulation of the intensity by the operator who monitors moment by moment the progress of the treatment and the endogenous heat triggered. Each frequency level respects this operating mode to avoid excessive heating.

Thus, T-SHAPE 2 device is substantially equivalent to its predicate devices.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, than the legally marketed predicate devices.