June 26, 2020

I.T.S. Group S.R.L.
% Chiara Violini
Consultant
Endo Engineering SRL
Via Del Consorzio, 41
Falconara Marittima, Ancona 60015
Italy

Re: K200736
Trade/Device Name: Stardust Med
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: March 11, 2020
Received: March 23, 2020

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 post-marketing 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)*

K200736

Device Name
STARDUST MED

Indications for Use *(Describe)*

STARDUST MED is indicated for use in aesthetic, surgical and cosmetic applications and in selective treatments required in the medical of dermatology and general and plastic surgery.

STARDUST MED is indicated for hair removal and permanent hair reduction.

Permanent hair reduction is defined as the long term, stable reductions in the number of hairs when measured at 6, 9 and 12 months after the completion of a treatment regime

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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	STARDUST MED	I.T.S. GROUP s.r.l. Via del Cerchio, 1 40012 Calderara di Reno (BO) - Italy

5 510(k) Summary

Introduction:

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

Applicant/ Manufacturer Name and Address:	I.T.S. GROUP s.r.l. Via del Cerchio, 1 40012 Calderara di Reno (BO) Italy
510(k) Contact Person:	Chiara Violini Consultant Email: c.violini@endoengineering.it Phone: +39-071-9156048 Fax: +39-071-0971883
Date Prepared:	11/03/2020
Device Name:	STARDUST MED
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery
Regulation number:	21 CFR 878.4810
Classification product code:	GEX
Predicate Device:	MT ONE DIAMOND- M&T SRL - K191942

Description of the device:

STARDUST MED is a laser emitting device that is operated with handpiece in contact with the skin.
STARSDUST MED comprises a main console unit and a handpiece that is triggered by means of footswitch or a finger switch.
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 handpiece:

- 808 nm Laser diode.

	STARDUST MED	I.T.S. GROUP s.r.l. Via del Cerchio, 1 40012 Calderara di Reno (BO) - Italy

Intended Use:

STARDUST MED is indicated for use in aesthetic, surgical and cosmetic applications and in selective treatments required in the medical of dermatology and general and plastic surgery.

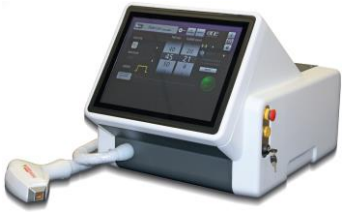
STARDUST MED is indicated for hair removal and permanent hair reduction.

Permanent hair reduction is defined as the long term, stable reductions in the number of hairs when measured at 6, 9 and 12 months after the completion of a treatment regime

Comparison of Technological Characteristics:

STARDUST MED utilizes technological characteristics (energy source, laser source, control mechanisms) and specifications that are similar to the Predicate Device.

	STARDUST MED	I.T.S. GROUP s.r.l. Via del Cerchio, 1 40012 Calderara di Reno (BO) - Italy

Specifications	Predicate Device	Device object of 510(k)
Device Name (K number)	MT ONE DIAMOND K191942	STARDUST MED
Submitter	M&T S.r.l.	ITS GROUP S.r.l.
Product Code	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810
Regulatory Class	II	II
Product Picture		
Mains	90-110 Vac / 190-230 Vac, 50 Hz/ 60 Hz	110-240 Vac, 50/60Hz
Intended use	MT ONE DIAMOND and its handpiece is indicated for use in aesthetic, surgical and cosmetic applications and in selective treatments required in the medical of dermatology and general and plastic surgery. MT ONE DIAMOND with HR808 nm laser handpiece is indicated for hair removal and permanent hair reduction. Permanent hair reduction is defined as the long term, stable reductions in the number of hairs when measured at 6, 9 and 12 months after the completion of a treatment regime	STARDUST MED is indicated for use in aesthetic, surgical and cosmetic applications and in selective treatments required in the medical of dermatology and general and plastic surgery. STARDUST MED is indicated for hair removal and permanent hair reduction. Permanent hair reduction is defined as the long term, stable reductions in the number of hairs when measured at 6, 9 and 12 months after the completion of a treatment regim
Wavelength	808 nm	808 nm
Fluence	Up to 90 J/cm^2	Up to 40 J/cm^2
Pulse duration	1 to 200 ms	10 to 300 ms
Mode	Cw/pulsed burst	Cw/pulsed burst
Repetition rate	Up to 10 Hz	1 to 10 Hz
Spot size	1.68 cm^2	1.0x1.0 cm

Performance data:

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

Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the STARDUST MED device.

The system complies with the IEC 60601-1, IEC 60601-2-22 standards for safety and the IEC 60601-1-2 standard 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".

Comparison of Intended Use:

STARDUST MED device's Intended Use is the same Intended Use of its predicate device.

Substantial Equivalence:

The STARDUST MED device has the same intended use, and similar technological characteristics and specifications, compared to the predicate device. Non-clinical testing supports that the device's technological characteristics and performance do not raise new questions regarding the device's safety and efficacy for its intended use. The STARDUST MED device is considered substantially equivalent to the predicate K191942 device..