October 6, 2017
M&T S.R.L
% Chiara Violini
Endo Engineering S.r.l.
via Del Consorzio, 41
Falconara Marittima, Ancona, Italy 60015

Re: K172413
Trade/Device Name: MT One
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, ONF
Dated: July 31, 2017
Received: August 10, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

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)*
K172413

Device Name
MT ONE

Indications for Use *(Describe)*
MT ONE and its Hand Pieces are intended 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 with HR808USnm Laser Handpiece is indicated for treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction*.
MT ONE with AC415-950USnm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of Inflammatory Acne (acne vulgaris) in skin types (I-V) to the Fitzpatrick Scale.
MT ONE with VLPL535-950USnm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of Benign Pigmented and Vascular Lesions in all skin types (I-VI) to the Fitzpatrick Scale.
MMT ONE with HR580-950USnm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the hair removal and permanent hair reduction* in all skin types (I-VI) to the Fitzpatrick Scale.
MMT ONE with SR580-950USnm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick Scale.
MMT ONE with HR635-950USnm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the hair removal and permanent hair reduction* in all skin types (I-VI) to the Fitzpatrick Scale.
MT ONE with Er-Yag2940USnm Laser Handpiece is indicated for use in soft tissue (skin and cutaneous tissue) such as, but not limited to:
Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).
MT ONE with Nd:YAG1064(LP)USnm Laser Handpiece is indicated for:
- Removal of unwanted hair, for stable long term, or permanent, hair reduction* through selective targeting of melanin in hair follicles;
- Removal or lightening of unwanted hair (with or without adjuvant preparation);
- Treatment of pseudofolliculitis barbae (PEB).

*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.

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5 510(k) Summary

Introduction:

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

Applicant/ Manufacturer Name and Address:	M&T S.R.L. Via Pietrarubbia 32/F Rimini – 47900 Italy
510(k) Contact Person:	Chiara Violini Consultant Email: c.violini@endoengineering.it Phone: +39-071-9156048 Fax: +39-071-0971883
Date Prepared:	03/10/2017
Device Name:	MT ONE
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, ONF
Predicate Devices:	Quanta Forte QUANTA SYSTEM SPA K152714 OMNIMAX S Sharplight Technologies Ltd K111303

Description of the device:
MT ONE is an Intense Pulsed Light (IPL) and laser emitting device that is operated with handpiece in contact with the skin.
MT ONE comprises a main console unit and several handpieces that are 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 handpieces:

- HR808USnm Laser diode;

- AC415-950USnm intense Pulsed Light;
- VLPL535-950USnm Intense Pulsed Light;
- HR580-950USnm Intense Pulsed Light;
- SR580-950USnm Intense Pulsed Light;
- HR635-950USnm Intense Pulsed Light;
- Er-Yag Laser 2940 nm;
- Nd:Yag LP Laser 1064 nm.

Intended Use:
MT ONE and its Hand Pieces are intended 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 with HR808USnm Laser Handpiece is indicated for treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction*.

MT ONE with AC415-950USnm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of Infiammatory Acne (acne vulgaris) in skin types (I-V) to the Fitzpatrick Scale.

MT ONE with VLPL535-950USnm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of benign Pigmented and Vascular Lesions in all skin types (I-VI) to the Fitzpatrick Scale.

MT ONE with HR580-950USnm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the hair removal and permanent hair reduction* in all skin types (I-VI) to the Fitzpatrick Scale.

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- Treatment of pseudofolliculitis barbae (PEB).

*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:
MT ONE has the same technological characteristics (energy source, laser/IPL source, control mechanisms) and specifications as its predicate devices.

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

Safety and electromagnetic compatibility (EMC)
The system complies with the IEC 60601-1, IEC 60601-2-22, IEC 60601-2-57 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 lndustry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Comparison of Intended Use:
MT ONE device's Intended Use is the same Intended Use of its predicate device.

Conclusion:
MT ONE device has the same intended use and same technological characteristics and specification as its predicate devices.

Thus, MT ONE device is substantially equivalent to its predicate device.