April 24, 2020

M&t Srl
% Chiara Violini
Consultant
Endo Engineering
Via Del Consorzio, 41
Falconara Marittaima, 60015 It

Re: K192856
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, ONG, ONF, ONE
Dated: September 19, 2019
Received: October 4, 2019

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 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,

Colin Kejing Chen, Ph.D.
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)*
K192856

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 specialties of dermatology and general and plastic surgery.

MT ONE with HR808nm Laser Handpiece is indicated for the treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction*.

MT ONE with AC415-950nm 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 VLPL535-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of benign Pigmented and Vascular Lesions in skin types (I-V) to the Fitzpatrick scale.

MT ONE with VLPL535-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) with Sub-Millisecond Technology (S.M.T.) is indicated for the treatment of erythematous rosacea, Telangiectasias, PWS (Port Wine Stains) Benign Pigmented Lesions (eg Mottled Pigmentation, Ephilides) and Benign Vascular lesion(eg Diffuse Redness).

MT ONE with HR580-950 nm 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 SR580-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick scale.

MT ONE with HR635-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for hair removal and permanent hair reduction* in all skin types (I-VI) to the Fitzpatrick scale.

MT ONE with HR635-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) In-Moving is indicated Hair removal and permanent Hair reduction in all skin types (I-VI) to the Fitzpatrick scale

MT ONE with 2940 nm Er-Yag 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 1064 nm Long Pulse (LP) Nd:YAG 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 and without adjuvant preparation)
• Treatment of pseudofolliculitis barbae (PFB)
• Benign vascular Lesions.

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

MT ONE with 532/1064 nm Nd:YAG Q-Switch Laser Handpiece is indicated for:

• Benign vascular and pigmented lesions, age spots
• Nevus spilus
• Tattoo removal

MT ONE with fractional non-ablative 1540 nm Er Glass Laser Handpiece is indicated for

• Post-operative Scars, Acne Scars, Skin Resurfacing, Striae

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:	Fiorenzo Rossi CEO Email: fiorenzor@medical-technology.it Phone: +39-0541-727486
Date Prepared:	20/04/2020
Device Name:	MT ONE
Common or Usual Name:	Intense Pulsed Light(IPL) and laser System
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation number:	21 CFR 878.4810
Classification product code:	GEX, ONG, ONF, ONE
Predicate Devices:	Icon - PALOMAR - K110907 Quanta Forte - QUANTA SYSTEM SPA - K152714 OmniMax S4- SHARPLIGHT TECHNOLOGIES LTD. - K111303 Harmony Xl - ALMA LASERS LTD. - K072564 M22 - LUMENIS LTD. - K142860 MT One- M&T SRL - K172413 K150907 ELLIPSE NORDLYS + K161162 ELLIPSE FRAX 1550 FOR NORDLYS- ELLIPSE A/S

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.

The main console of MT ONE is the same, with no modification, of the predicated devices cleared by K172413. The difference is only in the addition of 4 new handpieces, see list below.

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:

Handpieces that are already cleared by K172413

- HR808 nm laser diode
- AC415-950 nm Intense Pulsed Light
- VPLP535-950 nm Intense Pulsed Light
- SR580-950 nm Intense Pulsed Light
- HR580-950 nm Intense Pulsed Light
- HR635-950 nm Intense Pulsed Light
- 2940 nm ERBIUM YAG laser
- 1064 nm ND:YAGLP laser

Handpieces object of this submission:

- 532/1064 nm ND:YAG Q-Switched laser
- Fractional non-ablative 1540 nm Er:Glass laser
- VPLP535-950 nm Intense Pulsed Light with S.M.T.
- HR635-950 nm Intense Pulsed Light In Moving

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 specialties of dermatology and general and plastic surgery.

MT ONE with HR808nm Laser Handpiece is indicated for the treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction*.

MT ONE with AC415-950nm 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 VLPL535-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for the treatment of benign Pigmented and Vascular Lesions in skin types (I-V) to the Fitzpatrick scale.

MT ONE with VLPL535-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) with Sub-Millisecond Technology (S.M.T.) is indicated for the treatment erythematous rosacea, Telangiectasias, PWS (Port Wine Stains) Benign Pigmented Lesions (eg Mottled Pigmentation, Ephilides) and Benign Vascular lesion(eg Diffuse Redness).

MT ONE with HR580-950 nm 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 SR580-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick scale.

MT ONE with HR635-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) is indicated for hair removal and permanent hair reduction* in all skin types (I-VI) to the Fitzpatrick scale.

MT ONE with HR635-950 nm Intense Pulsed Light (IPL) Handpiece (with and without contact-cooling) In-Moving is indicated to Hair removal and permanent Hair reduction in all skin types (I-VI) to the Fitzpatrick scale.

MT ONE with 2940 nm Er-Yag 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 1064 nm Long Pulse (LP) Nd:YAG 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 and without adjuvant preparation)
- Treatment of pseudofolliculitis barbae (PFB)
- Benign vascular Lesions.

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

MT ONE with 532/1064 nm Nd:YAG Q-Switch Laser Handpiece is indicated for:

- Benign vascular and pigmented lesions, age spots
- Nevus spilus
- Tattoo removal

MT ONE with fractional non-ablative 1540 nm Er Glass Laser Handpiece is indicated for

- Post-operative Scars, Acne Scars, Skin Resurfacing, Striae

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

HR635-950 nm Intense Pulse Light IN-MOVING			
Specifications	Predicate device	Device object of 510(k)	Comparison to Predicate
Device Name (K number)	OMNIMAX S4 K111303	MT ONE K192856	
Wavelength	535-950 nm	635-950 nm	Equivalent to predicate device
Fluence	0.5 - 25 J/cm^2	5 - 8 J/cm^2	Equivalent to predicate device
Pulse duration	10 to 25 ms	6 ms	Equivalent to predicate device
Mode	Pulsed/burst	Pulsed/burst	Equivalent to predicate device
Repetition rate	0.4 to 1.25 Hz	0.4 to 1.25 Hz	Equivalent to predicate device
Spot size	6,4 cm^2	6,4 cm^2	Equivalent to predicate device
Intended use	Hair removal and permanent Hair reduction in all skin types (I-VI) to the Fitzpatrick scale	Hair removal and permanent Hair reduction in all skin types (I-VI) to the Fitzpatrick scale	Equivalent to predicate devices

VLPL535-950 nm Intense Pulse Light with S.M.T.			
Specifications	Predicate device	Device object of 510(k)	Comparison to Predicate
Device Name (K number)	ELLIPSE NORDLYS K150907 FRAX 1550 FOR ELLIPSE NORDLYS K161162	MT ONE K192856	
Wavelength	400-950 nm	535-950 nm	Equivalent to predicate device
Fluence	2-26 J/cm^2	0.5 - 25 J/cm^2	Equivalent to predicate device
Pulse duration	0.5 to 99,5 ms	0.5 to 99 ms	Equivalent to predicate device
Spot size	90 mm^2	6,4 cm^2	Equivalent to predicate device
Intended use	Treatment of Telangiectasias Treatment of Port Wine Stains Treatment of Benign Pigmented Lesions (eg Mottled Pigmentation, Ephilides) and Benign Vascular Lesions (eg Diffuse Redness) Treatment of Rosacea Treatment of Poikiloderma of Civatte Treatment of Inflammatory Acne Vulgaris	erythematous rosacea, Telangiectasias, PWS (Port Wine Stains) Benign Pigmented Lesions (eg Mottled Pigmentation, Ephilides) and Benign Vascular lesion(eg Diffuse Redness)	Equivalent to predicate device

Nd:YAG Q-S Laser 532/1064 nm					
Specifications	Predicate devices			Device object of 510(k)	
Device Name (K number)	HARMONY XL K072564	M22 K142860	OMNIMAX S4 K111303	MT ONE K192856	
Wavelength	532 (KTP)/1064 nm	1064 nm	532/1064 nm	532/1064 nm	Equivalent to predicate devices
Fluence		0.9 to 14 J/cm^2	Up to 0.8 J/cm^2	3,2 J/cm^2(532 nm) ϕ8 mm 4 J/cm^2(1064 nm) ϕ8 mm	Equivalent to predicate devices
Spot size (round)	1/2/3/4/5/6 mm 2.3 mm (KTP)	2/2.5/3.5/4/5/6/8 mm	2/4/6 mm	1, 2, 3, 4, 5, 8 mm	Equivalent to predicate devices
Pulse duration	20 ns	6 to 8 ns	10 ns	15 ns	Equivalent to predicate devices
Repetition rate		0.5 to 5 Hz	Up to 3 Hz smooth	Up to 10 Hz	Equivalent to predicate devices
Intended use	Non-invasive removal of various colored tattoos, as well as deep and superficial benign pigmented lesions	Pigmented lesions and tatoo removal	Pigmented lesions and tatoo removal.	Benign vascular and pigmented lesions, age spots and Nevus spilus, Tattoo removal	Equivalent to predicate devices

Fractional non-ablative Er-Glass Laser 1540 nm				
Specifications	Predicate devices		Device object of 510(k)	
Device Name (K number)	ICON K110907	ELLIPSE NORDLYS K150907 FRAX 1550 FOR ELLIPSE NORDLYS K161162	MT ONE K192856	
Wavelength	1540 nm	1550 nm	1540 nm	Equivalent to predicate devices
Fluence (milliJoule per microbeam	40 – 70 mJ/mB		70 mJ/mB (tip 100) 24 mJ/mB (tip 100)	Equivalent to predicate devices
Energy		5 – 100 mJ	7.7 J	Equivalent to predicate devices
Spot size (round)	10, 15 mm XDmicrolens	4-12 mm	- 10x10 mm square: MicroscopicThreatmentZones density 100; 10x10 mm square MicroscopicThreatmentZones density 324	Equivalent to predicate devices
Pulse duration	10-15 ms	1-20 ms	10-15 ms	Equivalent to predicate devices
Inteded use	Wrinkles, surgical scars, stretch marks, skin resurfacing and soft tissue coagulation	The Frax 1550 Laser (1550 nm) is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures	Post-operative Scars, Acne Scars, Skin Resurfacing, Striae,	Equivalent to predicate devices

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 hourss, 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 MT ONE device.
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 Industry 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.

Conclusions:
MT ONE device has the same intended use and same technological characteristics and specification as its predicate devices.
Moreover, MT ONE has been tested in accordance to consensus standard to demonstrate safety.
MT ONE device is as safe and effective as its predicate devices.
Thus, MT ONE device is substantially equivalent to its predicate device.