



October 17, 2019

M&T Srl
% Simonetta Strologo
Consultant
Endo Engineering Srl
Via Del Consorzio, 41
Falconara Marittima, 60015 It

Re: K191942
Trade/Device Name: MT One Diamond
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: June 13, 2019
Received: July 22, 2019

Dear Simonetta Strologo:

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,

Purva Pandya
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

Indications for Use

510(k) Number (if known)

K191942

Device Name

MT ONE DIAMOND

Indications for Use (Describe)

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.

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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	MT ONE DIAMOND	M&T s.r.l. Via della Fiera, 87 - 47900 Rimini
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510(k) Summary

Introduction:

This document contains the 510(k) Summary for the MT ONE DIAMOND 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:	Simonetta Strologo Consultant Email: s.strologo@endoengineering.it Phone: +39-071-9156048 Fax: +39-071-0971883
Date Prepared:	16/04/2019
Device Name:	MT ONE DIAMOND
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 Devices:	Quanta Forte - QUANTA SYSTEM SPA - K152714 MT One - M&T SRL - K172413

Description of the device:

MT ONE DIAMOND is a laser emitting device that is operated with handpiece in contact with the skin.
MT ONE DIAMOND 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:

- HR808 nm Laser diode.

	MT ONE DIAMOND	M&T s.r.l. Via della Fiera, 87 - 47900 Rimini
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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.

Comparison of Technological Characteristics:

MT ONE DIAMOND 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)

Electrical safety and EMC testing were conducted on the MT ONE DIAMOND 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:

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

Substantial Equivalence:

MT ONE DIAMOND device is as safe and effective as its predicate devices.

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

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