September 20, 2024

M&T S.r.l.
Fiorenzo Rossi
CEO
Via Pietrarubbia 32/F
Rimini, 47900
Italy

Re: K240604
Trade/Device Name: Mtone Evo (mtone Evo)
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: August 26, 2024
Received: August 26, 2024

Dear Fiorenzo Rossi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
Digitally signed by TANISHA L. HITHE -S
Date: 2024.09.20 14:33:24 -04'00'

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240604

Device Name

MTONE EVO (MTONE EVO)

Indications for Use *(Describe)*

MTONE EVO 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.
MTONE EVO with HR808nm and HR808 XL Laser Handpieces are indicated for the treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction*.
MTONE EVO with HR760/808/1060nm Laser Handpiece is indicated for Benign vascular and vascular dependent lesions removal (VL mode: frequency < 9 Hz) and temporary hair reduction (HR In-moving mode: frequency > = 9 Hz)

MTONE EVO 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.
MTONE EVO 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.
MTONE EVO 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).
MTONE EVO 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-V) to the Fitzpatrick scale.
MTONE EVO 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.
MTONE EVO 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-V) to the Fitzpatrick scale.
MTONE EVO 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-V) to the Fitzpatrick scale.
MTONE EVO 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).
MTONE EVO 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.
MTONE EVO with 532/1064 nm Nd:YAG Q-Switch Laser Handpiece is indicated for:
• Benign vascular and pigmented lesions, age spots
• Nevus spilus
• Tattoo removal

MTONE EVO 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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