October 24, 2024

Medency S.r.l.
Alessandro Zorgati
Regulatory Affairs Specialist
Via degli Ontani, 48
Vicenza, IT 36100
Italy

Re: K240543
Trade/Device Name: Rapido Medical Laser (Rapido MED, Rapido Derma, Rapido ENT, Rapido Podia)
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: September 23, 2024
Received: September 23, 2024

Dear Alessandro Zorgati:

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,

Yan Fu -S

Digitally signed by Yan Fu -S
Date: 2024.10.24 20:07:47 -04'00'

for

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240543

Device Name
Rapido Medical Laser (Rapido MED, Rapido Derma, Rapido ENT, Rapido Podia)

Indications for Use *(Describe)*
Rapido Medical Laser is generally indicated for use in incision, excision, vaporization, ablation, cutting and hemostasis, or coagulation of soft tissue in General surgery, Gynecology, Neurosurgery, Endovascular coagulation (EVLT/EVLA), Urology, Podiatry and Orthopedics, Dermatology, Plastic surgery and Aesthetics, Otolaryngology (ENT) and Oral surgery.

Rapido MED
Wavelength: 980nm
General surgery
– Rectal and anal hemorrohoidectomy
– Mastectomy
– Dermabrasion
– Appendectomy (open and laparscopic)
– Bowel resection (open and laparscopic)
– Colectomy
– Liver resection
– Resection of organs
– Thyriodectomy
– Adhesiolysis
– Hepatobiliary tumors
– Thoracotomy
– Cholecystectomy (open and laparscopic)
– Condyloma
– Breast biopsy
Neurosurgery
– Percutaneous Disc Decompression (PLDD)
– Discectomy
– Hemostasis in conjunction with meningiomas
Gynecology
– Cervical conization
– Myomnectomy
– Endometrial ablation
– Ovarian cystectomy
– Appendectomy
Endovascular coagulation (EVLT/EVLA)
– Endoluminal or endovenous laser surgery for saphenous veins (EVLA)
Urology
– Vaporization of urethral tumors
– Release of urethral stricture
– Removal of bladder neck obstruction
– Excision and vaporization of condyloma
– Lesions of external genitalia
– Vaporization of the prostate to treat benign prostatic hyperplasia (BPH).

Wavelength: 1470nm
- Vaporization, incision, excision, ablation, cutting and hemostasis
- Urology
- Plastic Surgery
- General Surgery
- Gynecology
- Endovascular coagulation
- Laser assisted lipolysis

Wavelength: 1940nm
- Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue

Rapido ENT
Wavelength: 810nm
Otolaryngology (ENT) and Oral surgery
– Removal of benign lesions from the ear, nose and throat
– Excision of carcinoma of the larynx
– Incision and excision of carcinoma in situ
– Neck dissection
– Laryngeal papillomectomy
– Removal of vocal cord/fold nodules, polyps and cyst

Wavelength: 450nm
- Incision, excision, vaporization, ablation, hemostasis and coagulation of soft tissue

Rapido PODIA
Wavelength: 1064nm
Podiatry
– Excision of periungual and subungual warts
– Excision of plantar warts
– Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophyte trichophyton rubrum and t. Mentagrophyte, and/or yeasts candida albicans, etc.)

Wavelength: 810nm
Orthopedics
– Coagulate

Rapido DERMA
Wavelength: 980nm
Dermatology/Aesthetics
– Photocoagulation of vascular & dermatological lesions of the face and extremities
– Photocoagulation of telangiectasia, veinulectasia of the legs and face
– Treatment of reticular veins and branch varicosities
– Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
– Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigments lesions as lentigines. Epidermal nevi, spider nevi.
– Dermatological surgery: Condyloma acuminate, warts, small non-malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasty and ulcers debridment.
– Seborrheic keratosis
– Mixoid cyst
– Papillary varix
– Acne treatment
Plastic surgery

– Cut, coagulation & vaporization
– Resurfacing non-contact
– Blepharopasty

Wavelength: 635nm
- Adjunctive use in providing temporary relief of nociceptive musculoskeletal pain

Wavelength: 1470nm
- Vaporization, incision, excision, ablation, cutting and hemostasis
- Coagulation of soft tissues
- Plastic Surgery
- Vascular lesions
- Dermatology
- Laser assisted lipolysis

Wavelength: 450nm
- Incision, excision, vaporization, ablation, hemostasis and coagulation of soft tissue

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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