



December 7, 2017

AMI Inc.
% Alexander Henderson
Official Correspondent, AMI, Inc.
BraunSolutions
970 South Dawson Way Unit 14
Aurora, Colorado 80012-3827

Re: K172908

Trade/Device Name: Q-Master Q-Switched Nd:YAG Laser System

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 18, 2017

Received: September 25, 2017

Dear Alexander Henderson:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

Indications for Use

510(k) Number (if known)

K172908

Device Name

Q-MASTER Q-Switched Nd:YAG Laser System

Indications for Use (Describe)

The Q-MASTER Q-Switched Nd:YAG Laser System is indicated for incision, excision, ablation and vaporization of soft tissue for general dermatology.

1064nm wavelength in Q-switched mode:

- Removal of dark ink (black, blue and brown) tattoos
- Treatment of nevus of Ota
- Treatment of common nevus
- Removal or lightening of unwanted hair
- Skin resurfacing procedures for the treatment of acne scars and wrinkles

1064nm wavelength in non Q-switched mode:

- Removal of unwanted hair, for stable long term, reduced hair growth when measured at 6, 9 and 12 months and for treatment of PFB (Pseudo Folliculitis Barbae). The laser is indicated for all skin types including tanned skin
- Photocoagulation and hemostasis of benign pigmented and benign vascular lesions, such as, but not limited to, port wine stains, hemaangioma, warts, telangiectasiae, rosacea, venous lake, leg veins and spider veins
- Coagulation and hemostasis of soft tissue
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532nm wavelength in Q-switched mode (nominal delivered energy of 585nm and 650nm with the optional 585nm and 650nm dye hand-piece):

- Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos
- Treatment of benign vascular lesions including, but not limited to:
 - port wine birthmarks
 - telangiectasiae
 - spider angioma
 - cherry angioma
 - spider nevus
- Treatment of benign pigmented lesions including, but not limited to:
 - café-au-lait birthmarks
 - solar lentigines
 - senile lentigines
 - Becker's nevus
 - freckles
 - common nevus
 - nevus spilus
- Treatment of seborrheic keratosis
- Treatment of post inflammatory hyperpigmentation
- Skin resurfacing procedures for the treatment of acne scars and wrinkles

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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