



September 15, 2023

Hooda Co.,Ltd.  
% Do Kim  
CEO  
BT Solutions, Inc.  
Unit 904, Eonju-ro 86-gil 5, Gangnam-gu  
Seoul, Seoul 06210  
Korea, South

Re: K231791

Trade/Device Name: PENTO Nd:YAG and Alexandrite 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: June 12, 2023  
Received: June 20, 2023

Dear Do Kim:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Colin K. Chen -S

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

510(k) Number (if known)

**K231791**

Device Name

PENTO Nd:YAG and Alexandrite laser system

Indications for Use (Describe)

The PENTO Nd:YAG and Alexandrite laser system is indicated for : the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

755nm Wavelength:

- Temporary hair reduction.
- Stable long-term or permanent reduction through selective targeting of melanin in hair follicles.
- Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime.
- 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.
- On all skin types (Fitzpatrick I- VI) including tanned skin.
- Treatment of benign pigmented lesions. Treatment of wrinkles.
- The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

1064nm Wavelength:

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB.
- 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.
- The lasers are indicated on all skin types Fitzpatrick I- VI including tanned skin.
- Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins.
- Coagulation and hemostasis of soft tissue.
- Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.
- The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Treatment of wrinkles.
- Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc).

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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