September 23, 2022

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

Re: K222555
Trade/Device Name: reepot 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 7, 2022
Received: September 9, 2022

Dear Do Hyun 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jianting Wang
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K222555

Device Name
reepot Nd:YAG laser system

Indications for Use *(Describe)*

The Reepot 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.
532nm Wavelength :
- Tattoo removal: light ink (red, tan, purple, orange, skyblue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Treatment of Lentigines
- Treatment of Cafe-Au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyper-Pigmentation
- Treatment of Becker's Nevi, Freckles and Nevi Spilus

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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K222555
Section 5 – 510(k) Summary

I. General Information [21 CFR 807.92(a) (1)]

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Contact Person:	Do Hyun Kim, BT Solutions, Inc. Unit 904, Eonju-ro 86gil 5, Gangnam-gu, Seoul 06210, Korea. Tel: +82-2-538-9140 Email: ceo@btsolutions.co.kr
Preparation Date:	August 17, 2022

II. Names [21 CFR 807.92 (a) (2)]

Trade or Proprietary Name	reepot Nd:YAG laser system		
Common Device Name(s) and Regulatory Class	**Product Code(s)**	**Classification Panel**	**Regulation**
Laser Powered Surgical Instruments (& Accessories) Class II	GEX	General & Plastic Surgery Panel, 79 (SU)	§ 878.4810, Laser surgical instrument for use in general and plastic surgery and dermatology
	Surgical Powered Lasers and Delivery Devices/Hand piece Accessories		

III. Predicate Devices [21 CFR 807.92(a) (3)]

K #	Predicate Device
K173038	CuRAS Nd:YAG Laser

IV. Product Description [21 CFR 807.92(a) (4)]

The reepot Nd;YAG laser system is comprised of the following major components:

1) Laser system console
2) LCD control panel
3) VSLS handpieces (included camera and LCD display)
4) Footswitch.
5) Accessories

The system is intended to be used in user facilities such as hospitals, physicians' offices and medical spas.

V. Intended Use and Indications for Use [21 CFR 807.92(a) (5)]

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

532nm Wavelength :
- Tattoo removal: light ink (red, tan, purple, orange, skyblue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Treatment of Lentigines
- Treatment of Cafe-Au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyper-Pigmentation
- Treatment of Becker's Nevi, Freckles and Nevi Spilus

VI. Summary of Technical Characteristics [21 CFR 807.92(a)(6)]

Table 1: Technical Comparison for the Q-switched Laser

Parameter	**reepot Nd;YAG laser system (K222555)**	**CuRAS Nd;YAG laser system (K173038)**
Product Code & Regulation No.	**GEX 21 CFR 878.4810**	**GEX 21 CFR 878.4810**
Laser Medium	Nd:YAG	Nd:YAG
Laser wavelength	532nm	1064nm/532nm
Output energy	Max 0.35J @532 nm	Max 1.6J @1064 nm Max 0.4J @532 nm
Pulse width	5-20ns	5-20ns
Repetition Rate	1-10Hz	1-15Hz
Spot size	4mm, 6mm	2mm-10mm
Aiming beam	Diode 635nm 5mW	Diode 635nm 5mW
User Interface	LCD touch screen	LCD touch screen
Optical guide	Articulated arm	Articulated arm

Electrical Requirements	220-230VAC, 50-60 Hz,	220-230VAC, 50-60 Hz,
Indications for Use	The reepot Nd;YAG laser system in indicated for : the incision,excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. 532nm Wavelength : - Tattoo removal: light ink (red, tan, purple, orange, skyblue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Treatment of Lentigines - Treatment of Cafe-Au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyper- Pigmentation - Treatment of Becker's Nevi, Freckles and Nevi Spilus	The CuRAS Nd;YAG laser system in indicated for : the incision,excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. 532nm Wavelength : - Tattoo removal: light ink (red, tan, purple, orange, skyblue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Treatment of Lentigines - Treatment of Cafe-Au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyper- Pigmentation - Treatment of Becker's Nevi, Freckles and Nevi Spilus

VII. Performance Testing [21 CFR 807.92(b)(1)]

IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for safety
IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance

IEC 60601-2-22 Medical Electrical Equipment-Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60825-1 Safety of laser products-Part 1: Equipment Classification, requirements and user's guide

In addition software verification and validation testing was performed and biocompatibility was established.

VIII. Clinical Data [21 CFR 807.92(b) (2)]

Based on the similarities in the safety and effectiveness profiles of the subject, reference, and primary predicate devices, no animal or clinical studies were deemed needed to support this submission.

IX. Conclusion

The reepot Nd;YAG laser system was found to be substantially equivalent to the predicate devices.

The reepot Nd;YAG laser system shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate device.