November 2, 2023

Beijing UNT Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, 102401
China

Re: K232532
Trade/Device Name: Nd:Yag Laser Therapy Systems
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: August 21, 2023
Received: August 21, 2023

Dear Ray Wang:

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.

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
Tanisha L. Hithe -S
2023.11.02
14:10:48 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232532

Device Name
Nd:Yag Laser Therapy Systems

Indications for Use *(Describe)*
Intended Use: The Nd: Yag Laser Therapy Systems 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 Benign Pigmented Lesions
-Removal of Minor Benign 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
1064nm wavelength:
-Tattoo removal: dark ink (black, blue and brown)
-Removal of Nevus of Ota
-Removal or lightening of unwanted hair with or without adjuvant preparation.
-Treatment of Common Nevi
-Skin resurfacing procedures for the treatment of acne scars and wrinkle

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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The assigned 510(k) Number: ____K232532____

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Submission: 2023/10/26

2. Sponsor Identification

Beijing UNT Technology Co., Ltd

M2-1 Area, Xinggu Development Zone, Pinggu District, Beijing, China 101200

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Nd:Yag Laser Therapy Systems

Common Name: Powered Laser Surgical Instrument

Regulatory Information
Classification Name: Powered Laser Surgical Instrument
Classification: II
Product Code: GEX
Regulation Number: 878.4810

Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

510(k) Number: K193477
Product Name: Nd:YAG Laser Therapy Systems
Manufacturer: Beijing Kes Biology Technology Co., Ltd.

6. Device Description:

Nd:Yag Laser Therapy Systems is a kind of laser pigment treatment instrument. It uses the principle of "photo-blasting". The laser emits high energy instantaneously, causing the pigment particles to absorb the laser energy and rapidly expand and rupture. Part of the pigment is broken down into smaller particles and excreted from the body, and the other part is swallowed by human macrophages and excreted through the lymphatic system.

The Nd:Yag laser therapy systems is mainly composed of a host, an operating hand tool and a foot switch. The operation hand is a treatment hand. The host is composed of a power module, a control module and a display module.

7. Indication For Use Statement:

Intended Use: The Nd: Yag Laser Therapy Systems 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 Benign Pigmented Lesions
-Removal of Minor Benign 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

1064nm wavelength:

-Tattoo removal: dark ink (black, blue and brown)
-Removal of Nevus of Ota
-Removal or lightening of unwanted hair with or without adjuvant preparation.
-Treatment of Common Nevi
-Skin resurfacing procedures for the treatment of acne scars and wrinkle

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device	Predicate Device K193477	Remark	Reference Device K202758
Device Name	Nd:Yag Laser Therapy Systems	ND:YAG Laser Therapy Systems	/	

Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	SAME	21 CFR 878.4810
Classification Panel	General & Plastic Surgery	General & Plastic	SAME	General & Plastic
Class	II	II	SAME	II
Product Code	GEX	GEX	SAME	GEX
Common Name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	SAME	Powered Laser Surgical Instrument
Indication for use	Intended Use: The Nd: Yag Laser Therapy Systems 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 Benign Pigmented Lesions -Removal of Minor Benign 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 1064nm wavelength: -Tattoo removal: dark ink (black, blue and brown) -Removal of Nevus of Ota -Removal or lightening of unwanted hair with or without adjuvant preparation. -Treatment of Common Nevi -Skin resurfacing procedures for the treatment of acne scars and wrinkle	The device 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 Benign Pigmented Lesions -Removal of Minor Benign 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 1064nm Wavelength: -Tattoo removal: dark ink (black, blue and brown) -Removal of Nevus of Ota -Removal or lightening of unwanted hair with or without adjuvant preparation. -Treatment of Common Nevi -Skin resurfacing procedures for the treatment of acne scars and wrinkle	SAME	The Nd: YAG Laser Therapy Systems is intended for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision,ablation, vaporization of soft tissue for general dermatology as follows: 532nm wavelength: -Removal of light ink (red, sky blue, green, purple, and orange) tattoo -Treatment of benign vascular lesions including, but not limited to: telangiectasias, -Treatment of benign epidermal pigmented lesions including, but not limited to: cafe-au-lait, solar lentiginos, senile lentiginos, Becher's, nevi Freckles, Nevus spilus, Seborrheic Keratoses -Treatment of Post Inflammatory Hyper-Pigmentation 1064nm wavelength: -Removal dark ink (black, blue and brown) tattoo -Removal of benign dermal pigmented lesions including, but not limited to: Nevus of OTA, Common Nevi, and Melasma,

				-Removal or lightening of unwanted hair with or without adjuvant preparation -Skin resurfacing procedures for the treatment of acne scars and wrinkles
Prescription use or not	Prescription use	Prescription use	SAME	Prescription use

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark	Reference Device K202758
Wavelength (nm)	1064nm and 532nm	1064nm and 532nm	SAME	1064 nm 532 nm
Aiming beam wavelength	650nm	635nm	Analysis	650 nm
Aiming laser output power	<5mW	5mW	SAME	/
Laser output mode	Q-switched pulse	Q-switched pulse	SAME	Q-switched pulse
Maximum pulse energy	1000mj~1064nm 500mj~532nm	@1064nmwavelength:1600mJ @532nm wavelength:400mJ	Analysis	1000mJ for 1064nm 500mJ for 532nm
Pulse Duration	4ns-6ns	5-10ns	Analysis	4ns-6ns
Spot Size	2~5mm	2mm-10mm	Analysis	2-10mm
Fluence range	1.02-31.80j/cm2for1064nm 0.50-15.90j/cm2for532nm	1064nm 0.4-51.0 J/cm2 532nm 0.4-12.7 J/cm2	Analysis	1.27 - 31.8 J/cm2 for 1064nm 0.6 - 15.9 J/cm2 for 532nm
Repetition rate	1~10hz	1-6Hz	Analysis	10 Hz Max.
Patient contact material	Aluminum	Aluminum alloy, ABS	Analysis	/

Table 3 Safety Comparison

ITEM	Proposed Device	Predicate Device	Remark	Reference Device K202758
Electrical Safety	Comply with ANSI/AAMI ES60601-1	Comply with IEC 60601-1	SAME	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME	Comply with IEC 60601-1-2
Laser Safety	Comply with IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-2-22	SAME	Comply with IEC 60601-2-22, IEC 60825-1
Biocompatibility				
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SAME	/
Irritation	No evidence of Irritation	No evidence of Irritation	SAME	/

Sensitization	No evidence of Sensitization	No evidence of Sensitization	SAME	/

Analysis：

Different - Aiming beam wavelength

The proposed device has different Aiming beam wavelength from the predicate device.

For the difference on Aiming beam wavelength between the predicate and proposed device(s), we can see that the proposed device has similar Aiming beam wavelength with predicate device (K193477). They are only with minor difference. And we think this minor difference will not affect the effectiveness and safety.

And the purpose of aiming beam is only for aiming. And at the same power, the difference in the wavelength of the aiming beam will only cause differences in visual color and brightness, and will not affect the effectiveness and safety. And aiming beam with a wavelength of 650nm is also common in laser products.

Different - Maximum pulse energy

The proposed device has different Maximum pulse energy from the predicate device.

The difference on Output Energy would not impact the safety and effectiveness, because the final safety and effectiveness about clinical indications will depends on the amount of energy output per unit area, which would produce thermal effects to the patient's skin area irradiated to achieve claimed indication for use. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety of the product can be ensured.

In addition, the reference device K202758 we have listed has the similar intended use as the proposed device, and the maximum pulse energy of reference device K202758 is consistent with the proposed device. Therefore, we believe that the maximum pulse energy of 1000mJ for 1064nm is a mature parameter that will not affect the safety and effectiveness of the equipment.

Different - Pulse Duration

The proposed device has different Pulse Duration from the predicate device.

Pulse Duration of proposed device is within the predicate device. And the proposed device has passed the

IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

Different - Spot size

The proposed device has different Spot size from the predicate device.

The difference on Spot size would not impact the safety and effectiveness, because the final safety and effectiveness about clinical indications will depends on the amount of energy output per unit area, which would produce thermal effects to the patient's skin area irradiated to achieve claimed indication for use. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety of the product can be ensured.

Different - Fluence range

The proposed device has different fluence range from the predicate device.

For the difference on fluence range between the predicate and proposed device(s), we can see that the

proposed device has similar fluence range with predicate device (K193477). The fluence range of 1064nm is within the predicate device. And the fluence range of 532nm only with minor difference. And we think this minor difference will not affect the effectiveness and safety. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

In addition, the reference device K202758 we have listed has the similar intended use as the proposed device, and the fluence range of reference device K202758 is also similar with the proposed device. The reference device has the same upper limits of the energy for 1064nm/532nm with the proposed device. And the lower limit of the energy for 1064nm/532nm is almost identical with the proposed device. Therefore, we believe that the fluence range of proposed device is a mature parameter that will not affect the safety and effectiveness of the equipment.

Different - Repetition rate
The proposed device has different Repetition rate from the predicate device.
Repetition rate of proposed device is higher than the predicate device. We think the effectiveness of the proposed device can be ensured. And the proposed device has also passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

In addition, the reference device K202758 we have listed has the similar intended use as the proposed device, and the repetition rate of the reference device K202758 is also 10Hz Max. The proposed device has the same repetition rate with the reference device. Therefore, we believe that the repetition rate 1-10Hz is a mature parameter that will not affect the safety and effectiveness of the equipment.

Different - Patient contact material
The proposed device has different patient contact material from the predicate device.
We have conducted the biocompatibility test included the cytotoxicity test, irritation test and sensitization test according to the judgment of 10993-1. Therefore, this difference will not affect safety and effectiveness of the proposed device.

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests

- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements
- IEC 60601-2-22: 2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Fourth edition 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device ND:YAG Laser Therapy Systems (K193477).