Beijing Kes Biology Technology Co., Ltd.
% Daina Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box. 120-119
Shanghai, 200120 Cn

June 24, 2020

Re: K193477
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: December 4, 2019
Received: December 16, 2019

Dear Daina Hong:

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,

Neil R.P. Ogden, MS
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193477

Device Name
Nd:YAG Laser Therapy Systems

Indications for Use *(Describe)*
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

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

The assigned 510(k) Number: K193477

1. Date of Preparation: 06/24/2020

2. Establishment Registration Number: 3009444646

3. Applicant

Name:	BEIJING KES BIOLOGY TECHNOLOGY CO., LTD.
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4. Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)
Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China
Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

5. Identification of the Proposed Device

Trade Name:	ND:YAG Laser Therapy Systems
Common Name:	Powered Laser Surgical Instrument
Model(s):	MED-810A
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification:	II
Product Code:	GEX
Regulation Number:	21 CFR 878.4810
Review Panel:	General& Plastic Surgery

6. Identification of Predicate Device

510(k) Number:	K173038
Product Name:	CuRAS Nd: YAG Laser

7. Device Description

The proposed device is a multi-wavelength, pulsed laser system designed for the treatment of benign pigmented lesions. The device can produce 1064nm and 532nm two different laser wavelengths to treat the different color skin. It consists of power supply module, microprocessor control module, laser treatment handpiece module, operation display module and cooling system module. The physician is able to select the desired wavelength and the related output energy via control panel.

8. Indications for Use

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

9. Substantially Equivalent (SE) Comparison

ITEM	Proposed Device	Predicate Device K173038
Product code	GEX	GEX
Class	II	II
Indications for use	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.	The CuRAS Nd; YAG laser systems 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 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	-Treatment of Common Nevi -Skin resurfacing procedures for the treatment of acne scars and wrinkle
Energy Source	Xenon Lamp	Xenon Lamp
Wavelength (nm)	1064nm and 532nm	1064nm and 532nm
Aiming beam wavelength	635nm	635nm
Aiming laser output power	5mW	5mW
Laser output mode	Q-switched pulse	Q-switched pulse
Maximum pulse energy	@1064nm wavelength:1600mJ @532nm wavelength:400mJ	@1064nm wavelength:1600mJ @532nm wavelength:400mJ
Pulse Duration	5-10ns	5~20ns
Spot Size	2mm-10mm	2mm-10mm
Fluence range	1064nm 0.4-51.0 J/cm2 532nm 0.4-12.7 J/cm2	Unknown
Repetition rate	1-6Hz	1-15Hz
Patient contact material	Aluminum alloy, ABS	Unknown
Biocompatibility		
Cytotoxicity	No Cytotoxicity	No Cytotoxicity
Sensitization	No evidence of Sensitization	No evidence of sensitization
Irritation	No evidence of Irritation	No evidence of irritation
Electrical Safety and EMC		
Electrical Safety	Comply with IEC 60601-1 IEC 60601-2-22,	Comply with IEC 60601-1 IEC 60601-2-22,
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2

10. Non-Clinical Testing

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

- IEC 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance;
- 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;
- IEC 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.
- ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Software Validation & Verification Test, documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Additionally, Bench Testing was conducted to verify the performance.

11. Clinical Testing

No clinical study is included in this submission.

12. Conclusion

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.