January 22, 2021

Medico USA Inc.
% Joyce Kwon
CEO
Provision Consulting Group Inc.
100 Barranca St. Suite 700
West Covina, California 91791

Re: K193266
Trade/Device Name: Miin
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: November 22, 2019
Received: November 26, 2019

Dear Joyce Kwon:

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,

Purva Pandya
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)*
K193266

Device Name
MIIN

Indications for Use *(Describe)*
MIIN, Q-Switched Nd: YAG Laser Therapy System (1064nm or 532nm) is indicated for use in incision, excision, ablation, vaporization of soft tissue for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis as follows:

1064 nm wavelength
• Tattoo Removal (dark ink: blue and black)
• Dermal Pigmented Lesions; including, but not limited to: Nevus of Ota, Lentigines, Nevi, Melasma and Cafe-au-lait
• Removal or lightening of hair with or without adjuvant preparation.
• Skin Resurfacing for Acne Scars and Wrinkles
• Benign cutaneous lesions; including, but not limited to: striac and Scars (excludes the 650nm wavelength)
• Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)

532 nm Wavelength
• Tattoo removal (light ink: red, sky blue, green)
• Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi
• Epidermal Pigmented lesions; including, but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis
• Skin Resurfacing for Acne Scars and Wrinkles
• Benign cutaneous lesions; including, but not limited to: striae and scars, (excludes the 6S0nm wavelength)
• Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)

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.

K193266
510(K) Summary

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Device Information

- Device Name: MIIN
- Classification Name: Powered Laser Surgical Instrument
- Common Name: Q-Switched Nd:YAG Laser System
- Classification: Class II
- Product Code: GEX
- Regulation number: 21 CFR 878.4810
- Date Prepared: 01/16/2021

Predicate devices

- Q-switched Nd:YAG Laser Therapy Systems (K133254)

Indication for use

MIIN, Q-Switched Nd: YAG Laser Therapy System (1064nm or 532nm) is indicated for use in incision, excision, ablation, vaporization of soft tissue for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis as follows:

1064 nm wavelength

- Tattoo Removal (dark ink: blue and black)
- Dermal Pigmented Lesions; including, but not limited to: Nevus of Ota, Lentigines, Nevi, Melasma and Cafe-au-lait
- Removal or lightening of hair with or without adjuvant preparation.
- Skin Resurfacing for Acne Scars and Wrinkles
- Benign cutaneous lesions; including, but not limited to: striac and Scars (excludes the 650nm wavelength)
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)

532 nm Wavelength

- Tattoo removal (light ink: red, sky blue, green)
- Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi
- Epidermal Pigmented lesions; including, but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis
- Skin Resurfacing for Acne Scars and Wrinkles
- Benign cutaneous lesions; including, but not limited to: striae and scars, (excludes the 6S0nm wavelength)
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)

Device Description

MIIN applies the Nd:YAG laser source and it is composed of main body part, hand piece part and arm part mainly. The main body part is consisted of laser module from which beam is irradiated, power module, control module and touch screen.

MIIN, The Q-Switched Nd:YAG Laser Systems is based on the Q-Switched Nd: YAG (1064nm) and frequency Nd: YAG (532nm) Laser Technology. There is one optical cavity containing the Nd: YAG Crystal

The MIIN Q-Switched Nd: YAG Laser Therapy Systems works based on laser selective photothermal therapy and blasting mechanism of Q-switched laser. Energy form particular wavelength with accurate dose will act on certain targeted color radicals: ink, carbon particles from derma and epidermis, exogenous pigment particles and endogenous melanophore from derma and epidermis. When suddenly being heated, pigment particles immediately blast into smaller pieces, which will be swallowed by macrophage phagocytosis and enters into lymph circulation system and finally be discharged out of body.

The physician is able to select the desired wavelength and the related output energy, spot size and fluency via control panel.

Substantial Equivalence Discussion

Specification	Predicate device	Proposed Device	Discussion of Differences
K Number	K133254	K193266	
Product Code	GEX		Identical
Manufacturer	Cynosure (HOYA ConBio)	LTRA Global Co., Ltd.	
Device Name	RevLite Q-Switched Nd: YAG Laser Systems	MIIN Q-Switched Nd: YAG Laser Systems	Similar
Intended use	Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis.		Identical
Indications for use	1064nm wavelength • Tattoo Removal (dark ink: blue and black)		Identical

	• Dermal Pigmented Lesions; including, but not limited to: Nevus of Ota, Lentigines, Nevi, Melasma and Cafe-au-lait • Removal or lightening of hair with or without adjuvant preparation. • Skin Resurfacing for Acne Scars and Wrinkles • Benign cutaneous lesions; including, but not limited to: striae and Scars (excludes the 650nm wavelength) • Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength) 532nm Wavelength • Tattoo removal (light ink: red, sky blue, green) • Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi • Epidermal Pigmented lesions; including, but not limited to: cafe-au-lait birthmarks, solar lentigines, senile lentigines, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis • Skin Resurfacing for Acne Scars and Wrinkles • Benign cutaneous lesions; including, but not limited to: striae and scars, (excludes the 6S0nm wavelength) • Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)		
Laser Medium	Nd: YAG	Nd: YAG	Identical
Operating Parameters	Q-Switched	Q-Switched	Identical
Energy Source	Xenon Lamp	Xenon Lamp	Identical
Wavelength (nm)	1064nm and 532nm		Identical

Specification	**Predicate device**	**Proposed device**	**Discussion of Differences**
Maximum Pulse Energy	@1064nm wavelength: 1500mJ @532nm wavelength: 450mJ	@1064nm wavelength: 3500mJ @532nm wavelength: 500mJ	Similar
Pulse Duration	7-20ns	25ns	Similar
Repetition Rate	1-10Hz	0-10Hz	Identical
Nominal ocular hazard distance	NOHD 3.3km	NOHD 93m	Less than Predicate device, safer
Spot Size	Adjustable Spot Size 2-8.5mm (Diameter)	Adjustable Spot Size 1-10mm (Diameter)	Wider adjustable range of spot size than predicate device, more useful

Beam delivery	Articulated Arm with Handpiece	Articulated Arm with Handpiece	Identical
Cooling	Internal distilled water circulating cooling	Internal distilled water circulating cooling	Identical
Anatomical Sites	Skin and subcutaneous tissue	Skin and subcutaneous tissue	Identical
Electrical Requirements	AC 230V, 50/60 Hz	AC 110-230V, 50/60Hz	Identical
Sterilization	Sterile	Non-Sterile	K152856 and K083203 share the same indication for use and technology with the subject device(K193266), the devices have not done sterilization for their handpiece tips.

Similarities

The subject device has same device characteristics with the Primary predicate devices (K133254) such as intended use, Indications for use, general shape (Design), structure, fundamental technologies, Operating Parameters, Laser medium, Wavelength, Pulse duration, repetition rate, spot size and Cooling method are similar. Technological characteristics are similar as predicate device. Testing including Biocompatibility tests (ISO 10993), Performance Testing (IEC 60825) and EMC Testing (IEC 60601-1, IEC 60601-1-2) has been finished to ensure the devices to comply with FDA Guidance on 'The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications'.

Differences

The difference between the subject device and the primary predicate device is maximum Pulse Energy. The max energy of Q-switch of MIIN (K193266) is 1400mJ(1064 S/25ns) and the long pulse energy is 3500mJ. The reference device K083889 has 1600mJ(5ns) (Q-switched) and 5000mJ (long pulsed). MIIN has lower pulse energy then its reference K083889, and does not raise any questions in safety and effectiveness in equivalence. For sterilization, K152856 and K083203 share the same indication for use and technology with the subject device(K193266), the devices have not done sterilization for their handpiece tips. It means that in all aspects, the subject device is equivalent in safety and effectiveness with predicate device. Therefore, this Maximum pulse energy difference doesn't affect device safety and effectiveness.

Conclusion

The MIIN Q-Switched Nd:YAG laser system constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental technology as its predicate devices. Therefore, MIIN Q-Switched Nd:YAG laser system and the predicate device are substantially equivalent.

Performance Data

Biocompatibility testing
The biocompatibility evaluation for the Q-Switched Nd: YAG Laser Therapy Systems was conducted in accordance with the guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The handpiece is considered skin and subcutaneous tissue contacting device.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the Q-Switched Nd: YAG Laser Therapy Systems. The device complies with the IEC 60601-1, standard for safety and the IEC 60601-1-2 standard for EMC.

Performance testing
Performance testing was conducted on the device according to IEC 60825-1.

Software Verification and Validation Testing
Software verification and validation testing were conducted, and 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." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

The subject device was tested to evaluate its performance as below.

- MIIN Q-switched Nd: YAG Laser System is tested and evaluated according to EN60601-1:2006+A1:2013 Medical electrical equipment Part 1: General requirements for basic safety and essential performance

- Effect to the device by electromagnetic disturbances were tested and evaluated according to the EN60601-1-2:2015 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance. All the results presented here demonstrated the requirements and tests for electromagnetic disturbances.

- MIIN Q-switched Nd: YAG Laser System is tested and evaluated according to EN60601-1-6:2010, AMD1:2015 Medical electrical equipment Part 1-6 General requirements for safety – Collateral Standard: Usability.

- MIIN Q-switched Nd: YAG Laser System is tested and evaluated according to EN 60601-2-22:2013 "Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment"

- Safety of laser products is evaluated according to IEC 60825-1: 2014. All the results presented here demonstrated the equipment classification and requirements.

- Risk management was recorded according standard ISO 14971: 2012. All the results presented here demonstrated the application of risk management to medical devices.

- Usability was documented according to standard EN 62366: 2008. All the results presented here demonstrated the application of usability engineering to medical devices.

- Biocompatibility was tested and evaluated according to FDA-recognized consensus standard ISO 10993-5: 2009 and ISO 10993-10: 2010.

Conclusion:

The non-clinical data support the safety of the device and the performance testing report demonstrate that the MIIN, the Q-Switched Nd: YAG Laser Therapy Systems should perform as intended in the specified use conditions. Medico considers the MIIN, the Q-Switched Nd: YAG Laser Therapy Systems to be substantially equivalent to the predicate device and does not raise any new issues of safety or effective