October 9, 2024

Medicreations LLC
Anthony Hardy
Chief Technology Officer
6370 Annie Oakley Drv
Las Vegas, Nevada 89120

Re: K231948
Trade/Device Name: Mediyag
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 14, 2024
Received: September 19, 2024

Dear Anthony Hardy:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
Digitally signed by TANISHA L. HITHE -S
Date: 2024.10.09 09:54:32 -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)*
K231948

Device Name
MediYag

Indications for Use *(Describe)*
The MediYag is indicated for:

532nm wavelength: treatment of benign pigmented lesions (Lentigines, Birthmark; Cafe-Au-Lait).

1064nm wavelength: treatment of acne scars, benign pigmented lesions (Nevus, Nevus of Ota), and removal of dark ink tattoos (black, blue).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K231948

This 510(k) Summary is being submitted for Medicreations LLC's MediYag Special 510(k) in accordance with requirement of 21 CFR 807.92.

The assigned 510(k) Number: K231948

1. Date of Preparation

10/01/2024

2. Sponsor

Medicreations LLC
6370 Annie Oakley Drive, Las Vegas, NV, 89120

Establishment Registration Number: 3012772112

Contact Person:	Anthony Hardy
Position:	Chief Technology Officer
Tel:	702-650-0002
Email:	anthonyh@medicreations.com

3. Submission Correspondent

Medicreations LLC
6370 Annie Oakley Drive, Las Vegas, NV, 89120

Name:	Yosemit Xolalpa Rosales
Position:	Lead Systems Engineer
Tel:	702-650-0002
Email:	yosemitx@medicreations.com

4. Proposed Device Identification

Trade Name: MediYag
Common Name: Powered Laser Surgical Instrument
Model: MYA

Regulatory Information

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification: Class II
Product Code: GEX
Regulation Number: 21 CFR 878.4810
Review Panel: General & Plastic Surgery

Indications for Use Statement:

The MediYag is indicated for:

532nm wavelength: treatment of benign pigmented lesions (Lentigines, Birthmark; Cafe-Au-Lait).

1064nm wavelength: treatment of acne scars, benign pigmented lesions (Nevus, Nevus of Ota), and removal of dark ink tattoos (black, blue).

5. Device Description

The MediYag is a laser system which delivers a laser at a wavelength of 1064nm or 532nm.

Table 1: Main Components Introduction

Component Name	Function
Main Unit	Main human-machine interface
Articulated Arm	Articulated arm for holding of Treatment Probe
Treatment Probe	Laser Delivery
Foot Pedal	Control light output

6. Predicate Device Identification

Primary Predicate Device:

510(k) Number:	K161926
Product Name:	ND YAG Q-switch Laser Therapy Machine
Manufacturer:	Beijing ADSS Development Co., Ltd

Secondary Predicate Device:

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

7. Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. Validation testing was performed to confirm that the subject device operates according to the noted specifications for energy output, repetition rate, pulse width, and spot size. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- 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 14971:2019 Medical devices - Application of risk management to medical devices

7a. Software Verification and Validation Testing

The test method outlined for the MediYag device system software is a comprehensive and structured procedure that evaluates the various aspects of its functionality, safety, and performance, including interaction and observation methods of the display functions, interface functions, factory parameters, and water flow and temperature display as well as alarm and cooling effect functions.

8. Clinical Testing

No clinical study is included in this submission.

9. Biocompatibility

No biocompatibility testing was necessary in this submission since the patient-contacting portions of the device are identical to those cleared under K161926.

10. Substantially Equivalent (SE) Comparison

Table 2: Comparison

Device & Predicate Devices	K231948	K161926	K193477
General Device Characteristics			
Product Code	GEX	GEX	GEX
Class	II	II	II
Regulation	878.4810	878.4810	878.4810
Laser Medium	Nd: YAG	Nd: YAG	Nd: YAG
Laser Type	Q-switched	Q-switched	Q-switched
Wavelength	1064 nm 532 nm	1064 nm 532 nm	1064 nm 532 nm
Output Energy	1064 nm: 100-1300 mJ 532 nm: 50-450 mJ	1064 nm: 100-1000 mJ 532 nm: 50-500 mJ	1064 nm: 1600 mJ 532 nm: 400 mJ
Maximum Energy Density	1064 nm: 41.4 J/cm^2 532 nm: 14.3 J/cm^2	1064 nm: 31.8 J/cm^2 532 nm: 15.9 J/cm^2	1064 nm: 51 J/cm^2 532 nm: 12.7 J/cm^2
Spot Size	2-10 mm	2-10 mm	2-10 mm
Pulse Width	5 ns	5 ns	5 - 10 ns
Repetition Rate	1-10 Hz	1-10 Hz	1-6 Hz

11. Substantially Equivalent Conclusion

The differences in the indications for use and technological characteristics between the subject and predicate devices do not raise new types of questions regarding safety and effectiveness, and the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.