September 27, 2024

Daeju Meditech Engineering Co., Ltd.
% Lee April
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K242206
Trade/Device Name: Activo
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: July 25, 2024
Received: July 29, 2024

Dear Lee April:

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: 2024.09.27 23:43:55 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242206

Device Name
ACTIVO

Indications for Use *(Describe)*
Incision, excision, ablation, vaporization of soft tissue for general dermatology (1064 nm)
Tattoo Removal: Dark ink (blue and black) (1064 nm)
Tattoo Removal: light ink (red, sky blue, green) (532 nm)
telangiectasias (532 nm)
spider nevi (532 nm)
solar lentiginos, senile lentiginos, becker's nevi, freckles (532 nm)
nevus of ota (1064 nm)

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 K242206

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Device Information
- Trade Name: ACTIVO
- Common Name: Laser Surgical Instrument
- Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Product Code: GEX
- Panel: General & Plastic Surgery
- Regulation Number: 21 CFR §878.4810
- Device Class: Class II
- Date prepared: 08/28/2024

Predicate Device
Primary Predicate
K152856, Helios III manufactured by Laseroptek Co., Ltd.

Indications for use
Incision, excision, ablation, vaporization of soft tissue for general dermatology (1064 nm)
Tattoo Removal: Dark ink (blue and black) (1064 nm)
Tattoo Removal: light ink (red, sky blue, green) (532 nm)
telangiectasias (532 nm)
spider nevi (532 nm)
solar lentiginos, senile lentiginos, becker's nevi, freckles (532 nm)
nevus of ota (1064 nm)

Device Description
The ACTIVO is based on the Nd:YAG(1064nm) and KTP Nd:YAG(532nm) laser technology.
It is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology.
Three basic elements of operations are as follows:
1) A Nd:YAG crystal is used as a gain medium which produces a laser beam.
2) A resonator then amplifies the beam.
3) A lamp that contains Xe gas is used, as a pumping light source. The lamp requires a high-pressure power source device for operation. When the electric energy generated from the high-pressure power source is induced into the electrode of the lamp, it converts into light energy(1064nm). This converted light energy pumps the Nd:YAG crystal – a gain medium – and the light exhausted from the crystal is amplified into a specific wavelength light(532nm). As it passes between the resonant gases, laser beam radiates to an output unit.

The regulation of laser output and repetition rate can be set by the user via GUI (Graphic User Interface) and controlled by microprocessor, which interfaces with the power supply.

Summary of Technological Characteristics

ITEM	PROPOSED DEVICE	PREDICATE DEVICE	Remark
	ACTIVO	Helios III	
K number	NA	K152856	SE
Product Code	GEX	GEX	SE
Regulation	21 CFR 878.4810	21 CFR 878.4810	SE
Indications for Use	Incision, excision, ablation, vaporization of soft tissue for general dermatology (1064 nm) Tattoo Removal: Dark ink (blue and black) (1064 nm) Tattoo Removal: light ink (red, sky blue, green) (532 nm) telangiectasias (532 nm) spider nevi (532 nm) solar lentiginos, senile lentiginos, becker's nevi, freckles (532 nm) nevus of ota (1064 nm)	Incision, excision, ablation, vaporization of soft tissue for general dermatology (1064 nm) Removal or lightening of unwanted hair with or without adjuvant preparation (1064nm) Tattoo Removal: Dark ink (blue and black) (1064 nm) Tattoo Removal: light ink (red, sky blue, green) (532 nm) port wine birthmarks (532 nm) telangiectasias (532 nm) spider angioma (532 nm) cherry angioma (532 nm) spider nevi (532 nm) cafe-au-lait birthmarks (532 nm) solar lentiginos, senile lentiginos, becker's nevi, freckles, nevus spilus (532 nm) nevus of ota (1064 nm)	Analysis 1
Laser Medium	Nd:YAG	Nd:YAG	SE
Operating Parameters	Q-Switched	Q-Switched	SE
Wavelength	1064nm / 532 nm	1064 nm / 532 nm	SE
Pulse Characteristics:			
Maximum Pulse Duration	10 ns	10 ns	SE
Energy Delivered	1.0 J (0.4J @ 532 nm) / pulse	1.3 J (0.5J @ 532 nm) / pulse	Analysis 2
Fluence	0.06-8J/cm2 @ 2 to 10 mm spot size	1 – 8 J/cm2 @ 1 to 8 mm spot size	Analysis 3
Spot Sizes	(Zoom, MLA) 2~10mm	(1064) 5 mm (532) 4 mm (Collimator) 8 mm (Zoom) 1~7 mm	Analysis 4
Repetition Rate	Single Shot, 1-10 Hz	Single Shot, 1 – 10 Hz	SE
Physical Characteristics:			
System Dimensions	40.2”(H) X 12.4”(W) X 32.5”(D)	36.8”(H) X 11.7”(W) X 32.2” (D)	Analysis 5
System Weight	198.4lbs	176 lbs.	
Electrical Requirements	110/220VAC, 50/60 Hz	AC 230 V, 50/60 Hz	

ITEM	PROPOSED DEVICE	PREDICATE DEVICE	Remark
Performance Specification Comparison			
Electrical safety	IEC 60601-1	IEC 60601-1	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	SE
Performance	IEC 60601-2-22	IEC 60601-2-22	SE

The subject and primary predicate device (K152856) are similar in indications, design, technology, functions, and principle of operation.

The differences between the subject and primary predicate are discussed as below:

Analysis 1 – Indications for Use
The indications for Use for both subject and predicate devices are not exactly same, however, indications of the subject device is in range of the indications of the predicate device; therefore, it does not affect the safety and effectiveness. They are substantially equivalent.

Analysis 2 – Energy Delivered
The Energy Delivered of the subject device is less than the predicate device. Energy Delivered is a key factor in Q-switched Nd:YAG laser therapy. The clinical parameters of ACTIVO we suggest are 50 – 750 mJ. Since this is covered by a maximum energy of 1,000mJ, it does not affect the effectiveness of the proposed device. Therefore, the difference on Energy Delivered is considered would not raise any issues in effectiveness.

Analysis 3 – Fluence
The minimum power is different.
The Fluence of the subject device is different from predicate device. The value is calculated as Energy Delivered/Spot size.
- Calculating the minimum power of the proposed device (based on maximum Spot size is 10 mm), 0.06 J/cm2 = 0.05/(0.5*0.5*3.14), 50 mJ is minimum Energy Delivered.
The minimum power of the subject device is lower than that of the predicate device.
The Fluence value is nothing more than a calculation of how much laser energy is per unit area.
For laser instrument, safety may be affected when the maximum power output. But the maximum power for the both devices are the same. Therefore, the difference in Fluence is considered would not raise any issues in safety and effectiveness.

Analysis 4 – Spot size
The Spot size of the subject device is larger than the Spot size of 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.
The Maximum laser output of the subject device is within the Maximum laser output of the predicate device. Therefore, the difference in Laser radiation range is considered would not raise any issues in safety and effectiveness.

Analysis 5 – System Dimension, System Weight and Electrical Requirements
The Weight, Dimensions and Electrical Requirements for the subject device is different from predicate device. However, the difference is just in electrical and physical specification and this difference will not raise any issues in safety and effectiveness. Thus, the difference is considered would not raise any issues in safety and effectiveness. And the proposed device has passed the IEC 60601-1, IEC 60601-2-22, IEC 60825-1 test and performance test in IEC 60601-1 test, the safety and performance of the product can be ensured.

Non-clinical Testing
Non-clinical tests were conducted to verify that the proposed device met all design specifications as was substantially equivalent (SE) to the predicate device.

Biocompatibility Testing
The biocompatibility evaluation for the subject device 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 including cytotoxicity, Sensitization and Irritation are conducted according to the ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Biocompatibility testing of ACTIVO is as below:
a) ISO 10993-5:2009 - Biological Evaluation of Medical Devices - Part 5: Tests for in vitro cytotoxicity
b) ISO 10993-10:2021 - Biological Evaluation of Medical Devices - Part 10: Tests for skin sensitization, 6.5 Guinea pig maximization test(GPMT)
c) ISO 10993-23:2021 - Biological Evaluation of Medical Devices - Part 23: Tests for irritation, 7.2 Animal irritation test by skin exposure

Electrical Safety and electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on Laser Surgical Instrument. The device complies with the following standards

- IEC 60601-1: 2005+A2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements

Particular Performance Testing
Performance testing was conducted on the device according to the following standard:

- IEC 60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Software Verification and Validation Testing
The software for this device was considered as a "Moderate" level of concern. 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".

Accuracy Testing
The accuracy test was conducted to verify that the max. energy, stability of energy, spot size, wavelength, and pulse duration of the proposed laser system do not deviate from the tolerance of the setting value or fixed value.
The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Clinical Testing
Not applicable.

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