May 19, 2026

Multi Radiance Medical, Inc.
Glenn Persello
Regulatory Affairs Manager
6521 Davis Industrial Pkwy.
Solon, Ohio 44139

Re: K254024/S001
Trade/Device Name: MR5 Activ Pro
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: NHN
Dated: April 17, 2026
Received: April 17, 2026

Dear Glenn Persello:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

CHUN XU -S

For Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254024/S001

Device Name

MR5 ACTIV PRO

Indications for Use *(Describe)*
The MR5 ACTIV PRO is indicated for adjunctive use in the temporary relief of pain associated with Lateral Epicondylitis.

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

Item	Information
Application Type	Traditional
Applicant	Multi Radiance Medical
Address	6521 Davis Industrial Parkway, Solon, OH 44139
Contact Person	Glenn Persello
Contact Information	gpersello@multiradiance.com • 440-542-0761
Preparation Date	May 19, 2026
Device Trade Name	MR5 Activ Pro
Common Name	Infrared Lamp
Classification Name	Powered Light-Based Laser Non-Thermal Instrument with Non-Heating Effect for Adjunctive Use in Pain Therapy
Regulation Number	890.5500
Product Code	NHN
Regulatory Class	Class II
Legally Marketed Predicate Device	FibroLux — K212189

Device Description:

The MR5 ACTIV Pro is a handheld, portable, reusable, battery-powered, non-invasive, non-sterile light-based therapy medical device that utilizes a single laser diode and multiple light emitting diodes (LEDs) to provide therapeutic infrared and visible red-light optical output through the device emitter aperture. The device platform includes optical sources at 905 nm, 850 nm, and 660 nm. For the Lateral Epicondylitis treatment mode that is the subject of this submission, the active optical outputs consist of a 905 ± 10 nm super-pulsed laser diode, 850 ± 15 nm infrared LEDs, and 660 ± 10 nm red LEDs. The device is designed to deliver localized optical energy through a fixed 4 cm^2 treatment aperture using predefined operating parameters consistent with a non-heating mechanism of action under product code NHN. The MR5 ACTIV Pro is a cordless, self-contained system powered by a rechargeable lithium-polymer battery and is intended for use in a clinical environment by trained healthcare professionals. The device incorporates software-controlled optical delivery parameters that regulate treatment duration, pulse repetition frequency, and synchronized emitter operation to ensure repeatable treatment delivery under labeled conditions.

Indications for use:

The MR5 ACTIV PRO is indicated for adjunctive use in the temporary relief of pain associated with Lateral Epicondylitis.

Intended Population:

The MR5 ACTIV PRO is intended for use in adults aged 22 years and older.

Technology Description

The MR5 ACTIV PRO utilizes a light-based therapy technology consisting of a 905 nm super-pulsed laser (SPL) combined with pulsed red (660 nm) and pulsed infrared (850 nm) light-emitting diodes (LEDs). Optical energy is delivered through a fixed 4 cm² treatment aperture using nanosecond super-pulsed laser emission together with electronically pulsed LED sources operating at defined duty cycles and time-averaged optical output levels. The device is configured to provide localized treatment for the temporary adjunctive relief of pain associated with Lateral Epicondylitis. Device operating parameters are controlled to maintain low duty-cycle optical exposure and safe skin temperature profiles, as demonstrated through performance and thermal testing described in this submission.

510(k) Summary Table — Technical Characteristics Comparison (Part 1)

Technological Characteristic	**Subject Device: MR5 ACTIV PRO (Lateral Epicondylitis Mode)**	**Predicate Device: FibroLux (K212189)**	**Equivalence Discussion**
Wavelength (nm)	• Laser: 905 ±10 nm • Red LED: 660 ±10 nm • IR LED: 850 ±15 nm	Not publicly available	Similar therapeutic wavelength ranges.
Number of Diodes	• Laser: 1 • Red LED: 3 • IR LED: 3	Not publicly available	Differences in diode count reflect device design and treatment geometry, with the subject device delivering energy through a smaller 4 cm² treatment aperture compared to the 30 cm² predicate aperture. Clinical performance data demonstrates that the device does not raise effectiveness concerns compared to the predicate device.
Peak Power (per diode)	• SPL: 50 W • Red LED: 133 mW • IR LED: 167 mW	Not publicly available	Peak laser power per SPL diode is identical between devices (50 W). Reported peak power values for the red and infrared LEDs represent characterization of instantaneous output during the active (ON) phase of pulsed operation. Thermal characterization testing and clinical performance data confirm that the device can be used as safely and effectively as the predicate device under the intended use conditions.
Average Power (per diode)	• SPL: 1.0875 mW • Red LED: 66.7 mW • IR LED: 83.3 mW	Not publicly available	SPL average power per diode differs due to pulse duration (87 ns vs 68 ns) while peak SPL power is identical at 50 W. The difference is small and remains in the milliwatt range. Total SPL average power is lower for the subject device because the subject has 1 SPL diode. and the predicate has 4 SPL diodes.

Net Average Power (Total Output)	•SPL: 1.0875 mW •Red LED: 200 mW •IR LED: 250 mW •Total: 451.0875 mW	Not publicly available	Predicate demonstrates higher total time-averaged optical output when calculated at a super pulsed laser repetition frequency of 250 Hz. The lower total output of the subject device reflects localized delivery through a smaller treatment aperture and does not raise increased effectiveness concerns compared to the predicate device, as supported by clinical performance data and thermal characterization testing.
Pulse Width*	•SPL: 87 ns •Red LED: 250 ms ON / 250 ms OFF • IR LED: 2 ms ON / 2 ms OFF	Not publicly available	Both devices utilize pulsed SPL, red LED, and infrared LED outputs. Differences in LED pulse timing reflect native operating frequency while maintaining equivalent 50% duty-cycle pulsed operation.

510(k) Summary Table — Technical Characteristics Comparison (Part 2)

Technological Characteristic	**Subject Device: MR5 ACTIV PRO (Lateral Epicondylitis Mode)**	**Predicate Device: FibroLux**	**Equivalence Discussion**
Pulse Repetition / Frequency	•SPL: 250 Hz •Red LED: 2 Hz •IR LED: 250 Hz	Not publicly available	Both devices use pulsed optical output with identical red LED frequency. The lower SPL and IR LED frequencies in the subject device do not raise effectiveness concerns compared to the predicate device because the subject device's operating configuration delivers clinically relevant optical dose to localized lateral epicondylitis targets through a smaller 4 cm² aperture. Clinical performance data and bench testing demonstrates that the device does not raise increased safety or effectiveness concerns compared to the predicate device.
Duty Cycle	•SPL: 0.00218% • Red LED: 50% • IR LED: 50%	Not publicly available	Both devices use extremely low SPL duty cycles and identical 50% LED duty cycles. The lower SPL duty cycle in the subject device does not raise effectiveness concerns because the complete operating configuration, including wavelength, average power, delivered energy, treatment time, treatment geometry, and LED contribution, was clinically validated for the temporary pain relief associated with lateral epicondylitis and bench thermal testing. Thermal bench testing data was submitted to demonstrate non-heating operation.
Spot Size(s)	•SPL: 0.44 cm² •Red LED: 4 cm² (aperture-based emission area) • IR LED 4 cm²	Not publicly available	SPL spot size per diode is equivalent. LED emission is divergent and fills the treatment aperture; therefore, LED spot size is appropriately represented by the treatment aperture area (4 cm² for the subject device and 30 cm² for the predicate device).

Laser Output Mode	Pulsed	Not publicly available	Same pulsed operating principle.
Laser Pulse Shape	Gaussian	Not publicly available	Same.
Laser Beam Profile	Elliptical (~9° × 25° divergence)	Not publicly available	Same optical beam geometry.
Aperture Size (Treatment Window)	4 cm^2	Not publicly available	Subject designed for localized treatment through a smaller treatment aperture; predicate designed for distributed coverage across a larger treatment aperture.
Irradiance	•SPL: 0.00027 W/cm^2 • Red: 0.050 W/cm^2 • IR: 0.0625 W/cm^2 • Total: 0.113 W/cm^2	Not publicly available	Higher calculated irradiance reflects localized delivery through a smaller 4 cm^2 treatment aperture compared to the 30 cm^2 predicate aperture. Total delivered energy remains comparable to or lower than the predicate device under indicated conditions. Clinical data and supplemental thermal characterization testing across Fitzpatrick Skin Types I–VI demonstrate safe operation under labeled conditions, with no adverse thermal events, burns, erythema, or tissue injury observed. Increased irradiance values reflect localized delivery through a smaller 4 cm^2 treatment aperture and do not result in increased thermal risk.
Total Fluence (per site)**	60 s exposure: •SPL 0.148 J/cm^2 • Red 3.0 J/cm^2 • IR 3.75 J/cm^2 • Total aperture-based fluence 6.77 J/cm^2	Not publicly available	Higher red, infrared, and total aperture-based fluence values reflect localized delivery through the 4 cm^2 treatment aperture, while SPL fluence remains lower than the predicate device. Total delivered energy per treatment site is lower for the subject device compared to the predicate under indicated conditions. Clinical data and supplemental thermal characterization testing demonstrate non-heating operation.
Total Energy Delivered (per site)	27.065 J/site	Not publicly available	Although the subject device delivers lower total energy per site than the predicate, the MR5 ACTIV PRO is intended for localized treatment of discrete lateral epicondylitis targets using a smaller 4 cm^2 treatment aperture and 60-second exposure. Clinical performance data submitted in this application demonstrates temporary pain relief under the subject device operating configuration. Therefore, the lower total energy per site does not raise increased effectiveness concerns compared to the predicate device.

Technological Characteristic	Subject Device: MR5 ACTIV PRO (Lateral Epicondylitis Mode)	Predicate Device: FibroLux (K212189)	Equivalence Discussion
Power Source	Li-polymer battery	Not publicly available	Same power source configuration.
Battery Capacity	4 Ah	Not publicly available	Same battery capacity.
Continuous Operation Time	6 hours	Not publicly available	Similar operating duration; no impact on safety or performance.
Battery Charging Time	4 hours	Not publicly available	Same battery charging time.
Device Dimensions	203 × 64 × 70 mm	Not publicly available	Similar device form factor.
Device Weight	250 g	Not publicly available	Similar handheld form factor.
Safety Classification	Class I laser	Not publicly available	Same laser safety classification.

510(k) Summary Table — Technical Characteristics Comparison (Part 3)

Table Footnote:
Output values for the MR5 ACTIV PRO are reported using the Lateral Epicondylitis treatment protocol (ACTIV PRO platform, 250 Hz SPL frequency, 60-second treatment duration per site). This is the only configuration clinically evaluated for the adjunctive use of temporary pain relief associated with Lateral Epicondylitis. The MR5 ACTIV PRO platform supports SPL frequencies from 5 Hz to 5000 Hz; however, only the 250 Hz configuration is in the scope of this 510(k). Other device platforms are 510(k)-exempt or outside the scope of this submission.

Pulse Timing Footnote:
For electronically pulsed LED emitters, pulse timing is determined by repetition frequency and duty-cycle operation rather than output power. At 50% duty cycle, the 660 nm red LED channel operating at 2 Hz produces a 0.5 second pulse period with 250 ms ON-time and 250 ms OFF-time in both devices. For the 850 nm infrared LED channel, the MR5 ACTIV PRO operating at 250 Hz produces a 4 ms pulse period with 2 ms ON-time and 2 ms OFF-time, while the predicate operating at 1000 Hz produces a 1 ms pulse period with 0.5 ms ON-time and 0.5 ms OFF-time. These timing differences reflect native operating configuration and pulse architecture, while optical output power remains an independent operating characteristic.

Fluence / Irradiance Calculation Basis Footnote:
The 905 nm SPL output is calculated using the SPL optical spot area because the SPL beam does not fill the full treatment aperture. For the MR5 ACTIV PRO, the SPL spot area is 0.44 cm^2. Red and infrared LED outputs are divergent and overfill the treatment aperture; therefore, red LED, infrared LED, and combined aperture-based irradiance/fluence values are calculated using the effective treatment aperture area: 4 cm^2 for MR5 ACTIV PRO.

510(k) Summary – Clinical Testing

Study Objective

The purpose of the supportive clinical study was to determine the effectiveness of the MR5 ACTIV PRO device for the temporary relief of pain associated with lateral epicondylitis.

Study Design

The study was a prospective, 1:1 randomized, triple-blind, placebo-controlled multi-center design.

Study Subject Population

A total of fifty (50) subjects completed the study across three (3) clinical study sites and randomized in a 1:1 ratio: 25 subjects randomized to receive the active device treatment and 25 subjects randomized to receive the placebo (sham) treatment. Subjects were adults diagnosed with unilateral lateral epicondylitis, evenly divided between genders, with 52% males (13/25) in the active treatment group and 48% (12/25) males in the placebo treatment group. The average subject age was 34.64 years for active group subjects and 35.12 years for placebo group subjects. At study entry, subject three-day average pain rating on the 0-100 Visual Analog Scale (VAS) for the affected lateral epicondyle was 79.36 for the active treatment group and 75.60 for the placebo treatment group.

Study Treatments

Subjects received six (6) treatment administrations with the MR5 ACTIV PRO device (active or sham) according to the defined protocol to the affected lateral epicondyle across a consecutive three-week period: two (2) treatments per week, each treatment three (3) to four (4) days apart. Subjects agreed to use only the medication(s), treatment(s) and therap(ies) determined during the individualized medication stabilization phase of the study to relieve any lateral epicondyle pain, as needed, throughout the study.

Study Results

Primary Effectiveness Endpoint

The primary effectiveness endpoint was the proportion of subjects achieving at least a 30% reduction in pain, as measured using the 0 to 100 Visual Analog Scale (VAS), at study endpoint relative to baseline. Primary efficacy success was predefined as the difference in the proportion of subjects between active and placebo groups who attained the primary effectiveness endpoint. Overall study success was predefined as at least a 30% difference in the proportion of individual subject successes between the active and placebo treatment groups.

The clinical study met its pre-defined primary effectiveness endpoint. The proportion of subjects meeting the primary effectiveness endpoint was larger in the treatment group than in the placebo group. As such, the study results support that the subject device is as effective as the predicate device for the temporary relief of pain associated with lateral epicondylitis.

Safety Outcomes

Two (2) of the 25 active treatment group subjects reported adverse events during the study: one (1) being a heat sensation and one (1) being a biting sensation. Both events were reportedly mild in intensity, fully resolved upon cessation of the treatment session, and were determined by the study investigator to be possibly related to application of the study device.

Conclusion
The clinical study findings demonstrate that the MR5 ACTIV PRO device is safe and effective as the predicate device for the temporary relief of pain associated with lateral epicondylitis.

Performance Testing

Verification and validation activities were successfully completed. Testing included evaluation of bench thermal testing, electrical safety, electromagnetic compatibility, software lifecycle processes, risk management, laser safety classification, and thermal performance.

Testing was conducted in accordance with the following recognized 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: Electromagnetic Disturbances — Requirements and Tests
- IEC 62304:2006 + A1:2015, Medical Device Software — Software Life Cycle Processes
- ISO 14971:2019, Medical Devices — Application of Risk Management to Medical Devices
- IEC TR 60601-4-2:2016, Electromagnetic Immunity Guidance and Interpretation
- IEC 60825-1:2014, Safety of Laser Products — Equipment Classification and Requirements

Biocompatibility assessment in accordance with "ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process", confirmed that all patient-contacting materials are biocompatible for their intended use.

Conclusions

The non-clinical data provided in this submission demonstrate that the MR5 ACTIV Pro complies with recognized standards for electrical safety, electromagnetic compatibility, software lifecycle processes, and risk management. Thermal characterization testing conducted under representative clinical ambient conditions and physiologic baseline skin temperature conditions demonstrated controlled skin surface temperature responses consistent with non-heating operation, with no burns, erythema, skin sensitivity, pigmentary alteration, blistering, or thermal tissue injury observed across Fitzpatrick Skin Types I through VI.

Clinical performance data further supports the use of the device for adjunctive use in the temporary relief of pain associated with Lateral Epicondylitis under labeled treatment conditions.

Based on the technological comparison, performance testing, thermal characterization, and clinical evidence provided in this submission, the MR5 ACTIV Pro is as safe and effective as the legally marketed predicate device K212189.