July 31, 2026

Led Intellectual Properties, LLC
Brian Purcell
Sr. Director, Global Regulatory Affairs and Quality
16552 Von Karman Ave.
Irvine, California 92606

Re: K261482
Trade/Device Name: LightStim for Wrinkles (1984); LightStim for Acne (2038)
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: OHS, OLP
Dated: May 5, 2026
Received: May 5, 2026

Dear Brian Purcell:

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.07.31 17:50:03 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261482

Please provide the device trade name(s).

LightStim for Wrinkles (1984);
LightStim for Acne (2038)

Please provide your Indications for Use below.

LightStim for Wrinkles is an Over-the-Counter device that is intended for the use in the treatment of full-face wrinkles.

LightStim for Acne is an Over-the-Counter device that is intended for the use in the treatment of mild to moderate inflammatory acne.

Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary K261482

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

I. SUBMITTER

LED Intellectual Property, LLC
16552 Von Karman Ave
Irvine, CA 92606
Contact person: Brian Purcell
Phone: (949) 502-4088
Date prepared: 4/17/2026

II. DEVICE

Name of the device: LightStim for Wrinkles, LightStim for Acne
Common or usual name: Light Therapy Device for Wrinkles and Acne
Classification name: Light-Based Over-the-Counter Wrinkle Reduction; Powered Light-Based Laser for Acne
Regulatory Class: 2
Product Code: OLP, OHS
Regulation: 21 CFR 878.4810

III. PREDICATE DEVICE

LightStim for Acne (K142246)- primary predicate. Product Code: OLP
LightStim for Wrinkles (K120775)- second predicate. Product Code: OHS
The predicate has not been subject to a design-related recall.

IV. Device Description

The LightStim for Wrinkles and LightStim for Acne are non-invasive, handheld LED-based phototherapy devices intended for dermatological treatment. The devices deliver non-coherent light energy through arrays of light-emitting diodes (LEDs) applied directly to the skin.

The LightStim for Wrinkles device emits light at wavelengths of 605 nm, 640 nm, 652 nm, and 850 nm and is intended for the treatment of full-face wrinkles. The LightStim for Acne device emits light at wavelengths of 417 nm and 640 nm and is intended for the treatment of mild to moderate inflammatory acne.

Both devices share a common design architecture consisting of an LED treatment array, embedded control electronics, a rechargeable battery, and a user interface that includes a single control button, a status indicator LED, and an audible signal. Treatment is initiated by a user button press and delivered for a predefined duration of approximately 3 minutes per treatment area, with an automatic shutoff after approximately 9 minutes of continuous operation.

The devices are powered by an internal rechargeable battery and are charged via a USB-C interface used solely for power delivery. The devices do not incorporate wireless communication, data storage, or external connectivity.

Embedded firmware controls treatment timing, operational states, and user interface functions, including enforcement of safety-related interlocks such as prevention of operation during charging and automatic termination of treatment upon connection to external power.
The optical output is controlled by hardware design, while software provides control of operational conditions and user interaction. The devices are intended for over-the-counter use in home environments.

V. Indications for Use

LightStim for Wrinkles is an Over-the-Counter device that is intended for the use in the treatment of full-face wrinkles.

LightStim for Acne is an Over-the-Counter device that is intended for the use in the treatment of mild to moderate inflammatory acne.

VI. Predicate Devices

- LightStim for Acne (K142246) – Primary predicate
- LightStim for Wrinkles (K120775) – Secondary predicate

The subject and predicate devices have the same intended use and utilize the same fundamental scientific technology (LED phototherapy).

A summary of the substantial equivalence between the subject device and the identified predicate devices is found in the table below.

VII. Technological Comparison Table

Table 19.1 – Substantial Equivalence

Feature	Subject Device	Predicate Device 1 LightStim for Wrinkles	Predicate Device 2 LightStim for Acne	Assessment
Device Type	LightStim for Wrinkles & LightStim for Acne	LightStim for Wrinkles	LightStim for Acne	Same
510(k) number	K261482	K120775	K142246	Similar
Product Code	OHS, OLP	OHS	OLP	Same

Feature	Subject Device	Predicate Device 1 LightStim for Wrinkles	Predicate Device 2 LightStim for Acne	Assessment
Energy Type	Non-coherent light	Non-coherent light	Non-coherent light	Same
Wavelengths	605, 640, 652, 850 nm (Wrinkles) 417, 640 nm (Acne)	605, 630, 660, 855 nm	410, 645 nm	Similar (Note 1)
Indications	Full Face Wrinkles Mild to Moderate Inflammatory Acne	Full Face Wrinkles	Mild to Moderate Inflammatory Acne	Same
Irradiance (@treatment distance)	21.6 mW/cm2 (Wrinkles) 18.0 mW/cm2 (Acne)	19.9 mW/cm2	50.8 mW/cm2 (Note 2)	Similar (Note 2)
Fluence (Dosage)	3.89 J/cm2 @ 3 min (Wrinkles) 3.24 J/cm2 @ 3 min (Acne)	3.58 J/cm2 @ 3 min	9.14 J/cm2 @ 3 min (Note 2)	Similar (Note 2)
Optical Output	Meets IEC 60601-2-83:2019 + A1:2022 limits	Meets IEC 60601-2-83:2019	Meets IEC 60601-2-83:2019 limits	Same
Treatment Duration	3 min/area	3 min/area	3 min/area	Same
Automatic Shutoff	Yes (9 min max)	Yes (30 min max)	Yes (30 min max)	Similar
User Interface	Single button + LED	Single button + LED	Single button + LED	Same
Power Source	Lithium Battery (USB-C)	AC Mains/DC	AC Mains/DC	Similar

Feature	Subject Device	Predicate Device 1 LightStim for Wrinkles	Predicate Device 2 LightStim for Acne	Assessment
Home Use	Yes	Yes	Yes	Same
Software	Class A	Class A	Class A	Same
Applied Part	Type BF	Type BF	Type BF	Same
Biocompatibility	ISO 10993-1:2025 ISO 10993-5:2009 – Cytotoxicity ISO 10993-10:2021 – Sensitization ISO 10993-23:2021 – Irritation	10993-1 Compliant	10993-1 Compliant	Same
EMC/Safety	IEC 60601-1:2005+A1:2012 + A2:2020 Ed. 3.2 ANSI/AAMI IEC 60601-1-2:2014+A1:2021 IEC 60601-1-11:2015 + A1:2020 IEC 60601-2-83:2019 + A1:2022 IEC TS 60601-4-2:2024 IEC 60601-1-6:2010 + A1:2013 + A2:2020 ISO 14971:2019 + A11:2021	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 60601-1-6	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 60601-1-6	Same

Note 1:

The subject devices and predicate devices have minor variations in wavelengths. The wavelength differences are inconsequential and fall within measurement error. These minor variations do not raise any new safety and effectiveness issues.

Note 2:

The subject Acne device delivers an irradiance of approximately 18.0 mW/cm² and a fluence of approximately 3.24 J/cm² per 3-minute treatment interval, compared to higher irradiance and fluence values in the earlier Acne device versions.

These values remain within the range of irradiance and fluence levels commonly used in LED-based phototherapy devices for dermatological applications, including those of predicate devices and values reported in the scientific literature.

The subject device maintains the same fundamental mechanism of action as the predicate devices, delivering non-coherent light energy within established therapeutic wavelength ranges to achieve the intended clinical effect.
Treatment is delivered in controlled, repeatable intervals (approximately 3 minutes per treatment area), consistent with predicate devices. The overall treatment paradigm, including duration per treatment area and recommended frequency of use, supports delivery of sufficient energy to achieve the intended therapeutic outcome.
The reduced irradiance and fluence represent a design optimization that supports device performance and user safety while maintaining effectiveness. This change does not alter the intended use, mechanism of action, or fundamental operating principles of the device.
The delivered optical output remains comparable to predicate devices within measurement tolerance and established therapeutic ranges.
Based on these considerations, the differences in irradiance and fluence do not raise new questions of safety or effectiveness.

VIII. Performance Testing

The devices were evaluated through non-clinical testing and found to meet applicable safety and performance requirements:

- **Electrical Safety. / EMC**:
  IEC 60601-1:2005+A1:2012 + A2:2020 Ed. 3.2
  IEC 60601-1-2:2014 + A1:2020 Ed. 4.1 (equivalent to ANSI/AAMI IEC 60601-1-2:2014+A1:2021)
  IEC 60601-1-11:2015 + A1:2020
- Optical / Photobiological Safety:
  IEC 60601-2-83:2019 + A1:2022,
  IEC 62471:2006
- **Software Verification & Validation**: Basic Documentation Level
  All requirements met; hazards mitigated
- **Biocompatibility**:
  Evaluated per ISO 10993-1:2025 (intact skin, limited duration)
  No new testing required based on risk assessment
- **Usability:**
  Evaluated per IEC 60601-1-6:2010 + A1:2013 + A2:2020 and FDA Human Factors Guidance
- **Risk Management**
  Complies with ISO 14971:2019+A11:2021

IX. CONCLUSIONS

Based on the comparison of intended use, technological characteristics, and performance testing, the subject devices have the same fundamental scientific technology as the predicate devices. The identified differences do not raise new questions of safety or effectiveness.

Therefore, the LightStim for Wrinkles and LightStim for Acne are substantially equivalent to the legally marketed predicate devices.