March 4, 2026

Radcliffe Watts, LLC
Dan Smith
Chief Executive Officer
201 E 5th St.
Mansfield, Ohio 44902

Re: K253871
Trade/Device Name: Klär Lite (RCW-KL1000)
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: November 23, 2025
Received: December 4, 2025

Dear Dan Smith:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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: 2026.03.04 15:46:19 -05'00'

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.	K253871

Please provide the device trade name(s).

Klär Lite (RCW-KL1000)

Please provide your Indications for Use below.

The Klär Lite is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leukoderma on all skin types (I-VI).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253871

510(k) Summary

Prepared on: 2025-12-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Radcliffe Watts, LLC
Applicant Address	201 E 5th St Mansfield OH 44902 United States
Applicant Contact Telephone	714-292-5532
Applicant Contact	Mr. Daniel Smith
Applicant Contact Email	admin@radcliffewatts.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Klär Lite (R CWKL10 00)
Common Name	Ultraviolet lamp for dermatologic disorders
Classification Name	Light, Ultraviolet, Dermatological
Regulation Number	878.4630
Product Code(s)	FTC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K170489	Clarify Medical Phototherapy System	FTC

Device Description Summary

21 CFR 807.92(a)(4)

The Klär Lite is a narrowband UVB light emitting phototherapy medical device intended for treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leukoderma on all skin types (I-VI).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Klär Lite is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leukoderma on all skin types (I-VI).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications of use are the same between this device and predicate/reference devices.

Technological Comparison

21 CFR 807.92(a)(6)

Please reference the attached document.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The Klär Lite phototherapeutic device was evaluated through a comprehensive series of non-clinical tests to support a determination of substantial equivalence with the predicate device.

Electrical and Mechanical Safety:
Testing was performed in accordance with IEC 60601-1:2012 (Edition 3.1) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, and IEC 60601-1-11:2015 Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment for home-use medical electrical equipment. All results demonstrated compliance with requirements for protection against electrical shock, mechanical hazards, fire, and thermal safety.

Electromagnetic Compatibility (EMC):
Conducted per IEC 60601-1-2:2014 (Edition 4.0) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. The device met all emissions and immunity limits including ESD, radiated/conducted RF, EFT/Burst, Surge, Power Frequency Magnetic Field, and Voltage Dips/ Interruptions.

Photobiological Safety and Performance:
Evaluated per IEC 62471:2006 Photobiological safety of lamps and lamp systems and ISO 15004-2, confirming the emitted optical radiation is within safe exposure limits for intended therapeutic use.

Biocompatibility:
Evaluated per the ISO 10993 series (specifically ISO 10993-1, Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process. Part 5: Tests for in vitro cytotoxicity, Part-10, Tests for skin sensitization, and Part-11: Tests for systemic toxicity. Tests confirmed the safety of all patient-contacting materials for intact skin contact, including cytotoxicity, sensitization, and irritation testing performed under GLP conditions.

Software Verification and Validation:
Conducted in accordance with IEC 62304:2006 + AMD 1:2015, Medical device software — Software life cycle processes, supporting software reliability and safety at the determined risk classification with basic level of documentation.

Risk Management:
Completed per ISO 14971:2019 Medical devices — Application of risk management to medical devices, to ensure identified hazards are effectively controlled and residual risk is acceptable.

Labeling and Usability:
Evaluated per IEC 62366-1:2015 EC 62366-1:2015 and validated through formative and summative usability studies.

Collectively, these tests demonstrate that Klär Lite meets applicable FDA-recognized consensus standards.

Clinical testing was not required to establish substantial equivalence for the Klär Lite phototherapeutic device.

The results of all nonclinical verification and validation testing demonstrate that the Klär Lite phototherapeutic device is as safe and effective.

Conclusion: The Klär Lite device is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.

Feature	Predicate Device – Skylit Phototherapy System (K170489)	Subject Device – Klär Lite K253871	Comparison Result
Technology Type	Narrowband UV-B LED phototherapy	Narrowband UV-B LED phototherapy	Identical
Wavelength	300-320 nm	311 ± 2 nm (UV-B) (nominal peak within UV-B emission range 295-320 nm)	Comparable
Light Source	LED array	LED array	Identical
Output Irradiance	3.0–15.0 mW/cm^2	3.0–5.0 mW/cm^2	Within Predicate Range
Treatment Area	4.5 cm^2	5.08 cm x 5.08 cm	Comparable
Exposure Control	Software-controlled timer and preset dose by skin type	Microcontroller algorithm with skin-type presets and real-time temperature feedback	Equivalent / Enhanced
Safety Features	Optical filter, thermal shutdown, firmware interlocks	Optical filter, integrated thermal sensor with auto-shutdown	Comparable
Applicator Type	Handheld home-use applicator with comb guide	Handheld home-use applicator with integrated diffuser	Equivalent
Operating Modes	Preset and manual	Preset and manual with temperature-compensated dose control	Equivalent / Enhanced
Cleaning Method	70 % IPA wipe (per IFU)	Validated 70 % IPA wipe per (RFV-1010A, CEV-1010A, SLJ-1010A) – no material damage	Equivalent / Enhanced

Power Input	Rechargeable battery or DC supply	Medical-grade DC supply	Comparable
Software Classification	IEC 62304 Class B	IEC 62304 Class B	Identical
Biocompatibility	ISO 10993 tested for skin contact	ISO 10993 tested for skin contact	Identical
Electrical Safety	IEC 60601-1 Ed 3.1	IEC 60601-1 Ed 3.1	Identical
EMC	IEC 60601-1-2 Ed 4.0	IEC 60601-1-2 Ed 4.0	Identical
Photobiological Safety	IEC 62471	IEC 62471	Identical
Usability Engineering	IEC 62366-1	IEC 62366-1	Identical
Prescription Status	Rx-only	Rx-only	Identical

Figure 1. Skylit Phototherapy System (K170489)

Figure 2. Subject Device – Klär Lite Phototherapy System