April 18, 2025

iSMART Developments LTD
Susan D'arcy
Managing Director
129 Green Lanes, Wylde Green
Birmingham, B73 5LT
United Kingdom

Re: K250224
Trade/Device Name: handLITE (TN19S)
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: ONE
Dated: January 15, 2025
Received: January 27, 2025

Dear Susan D'arcy:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.04.18 17:22:49 -04'00'

for 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250224

Device Name
handLITE (TN19S)

Indications for Use *(Describe)*
The handLITE is intended to emit energy in the red and near infrared region of the light spectrum, is generally indicated to treat dermatological conditions and specifically indicated to treat contact dermatitis of the hand and wrist.

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.

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510(k) Summary -K250224

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

Submitter's Name:	iSMART Developments LTD
Submitter's Address:	129 Green Lanes, Wylde Green, Birmingham, B73 5LT United Kingdom
Contact Person:	Susan D'Arcy
Telephone:	+44 (0) 7880313315
Date Prepared:	March 28, 2025
Device Trade Name:	handLITE Light-Emitting Diode (LED) Device (TN19S)
Common Name	Powered Light-Based Non-Laser Surgical Instrument
Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation	21 CFR 878.4810
Product Code	ONE
Review Panel	General & Plastic Surgery
Device Class	Class II

Predicate Devices

K171055	Philips Blue Control
K191629	faceLITE LED Mask

Intended Use

The handLITE is intended to emit energy in the red and near infrared region of the light spectrum, is generally indicated to treat dermatological conditions and specifically indicated to treat contact dermatitis of the hand and wrist.

Device Description

The handLITE device consists of:

1. Flexible silicone glove with integrated controller (contains rechargeable lithium-ion polymer batter)
2. Power supply and country specific adaptors

handLITE is a home use wearable light emitting diode (LED) phototherapy device.

The device consists of a flexible silicone glove that contains red (630nm) and near infrared (830nm) light emitting diodes (LEDs) and an integrated controller. The LEDs generate the light at an intensity of 30mW/cm^2, delivering 18J/cm^2 per treatment.

The power supply is used to charge the integrated Lithium battery in the handLITE.

Substantial Equivalence Discussion

Substantial Equivalence

The handLITE LED Device is substantially equivalent to the Philips BlueControl (K171055) and faceLITE LED Mask (K191629).

Description	**Subject device** **handLITE (TN19S)**	**Predicate** **Philips BlueControl K171055**	**Predicate** **faceLITE LED mask K191629**	**Significant differences**
Device manufacturer	ISMART DEVELOPMENTS LTD	Philips Electronics Nederland B.V.	iSMART Marketing SVCS Ltd	N/A
Device classification name	Powered Light-Based Non-Laser Surgical Instrument	Powered Light-Based Non-Laser Surgical Instrument	Light Based Over the Counter Wrinkle Reduction	**BlueControl:** Same **faceLITE:** Different due to indication
Device product code	ONE	ONE	OHS	**BlueControl:** Same **faceLITE:** Different code due to indication
Regulation	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	**BlueControl:** Same **faceLITE:** Same

Description	Subject device handLITE (TN19S)	Predicate Philips BlueControl K171055	Predicate faceLITE LED mask K191629	Significant differences
Device classification	Class II	Class II	Class II	**BlueControl:** Same **faceLITE:** Same
Prescription/OTC	Prescription use	Prescription use	Over the counter	**BlueControl:** Same **faceLITE:** Different
Use environment	Home use	Home use	Home use	**BlueControl:** Same **faceLITE:** Same
Intended user	Lay user	Lay user	Lay user	**BlueControl:** Same **faceLITE:** Same
Intended patient population	Adults with mild to moderate contact dermatitis on the hands or wrists	Adults over the age of 18 with mild to moderate psoriasis vulgaris	Adults with facial wrinkles	**BlueControl:** Similar **faceLITE:** Similar

Description	Subject device handLITE (TN19S)	Predicate Philips BlueControl K171055	Predicate faceLITE LED mask K191629	Significant differences
Intended Use and Indications for Use	The handLITE is intended to emit energy in the red and near infrared region of the light spectrum, is generally indicated to treat dermatological conditions and specifically indicated to treat contact dermatitis of the hand and wrist.	The Philips BlueControl is intended to emit energy in the blue region of the spectrum, is generally indicated to treat dermatological conditions and specifically indicated to treat mild psoriasis vulgaris.	The faceLITE LED mask is an over-the-counter device that is intended for the use in the treatment of full-face wrinkles.	**BlueControl:** Same use and general indication, similar specific indication **faceLITE:** Same use, different indications
Intended location of use	Hand and wrist (dorsal and palmar aspects)	Extremities[1]	Face	**BlueControl:** Similar, subject device treats specific area that is within the intended areas of predicate **faceLITE:** Different
Energy source	Light emitting diodes	Light emitting diodes	Light emitting diodes	**BlueControl:** Same **faceLITE:** Same

[1] Treatment area was not specified in K171055, treatment area as per Kleinpenning, et al. (2012), Efficacy of blue light vs. red light in the treatment of psoriasis: a double-blind, randomized comparative study. *Journal of the European Academy of Dermatology and Venereology*, 219-225 and manufacturer instructions for use.

Description	Subject device handLITE (TN19S)	Predicate Philips BlueControl K171055	Predicate faceLITE LED mask K191629	Significant differences
Peak wavelength (FWHM)	Red: 630nm ± 10nm NIR: 830nm ± 10nm	Blue: 452nm ± 7nm	Red: 630nm ± 10nm NIR: 830nm ± 10nm	**BlueControl:** Different wavelength/color band **faceLITE:** Same
Intensity	30mW/cm^2 total	40mW/cm^2 ± 5mW/cm^2	30mW/cm^2 total	**BlueControl:** Similar intensity **faceLITE:** Same
Treatment time	600 seconds (10 minutes)	1800 seconds (30 minutes)	600 seconds (10 minutes)	**BlueControl:** Subject device treatment time is shorter **faceLITE:** Same

Description	Subject device handLITE (TN19S)	Predicate Philips BlueControl K171055	Predicate faceLITE LED mask K191629	Significant differences
Treatment protocol	5× weekly, 6 weeks	A full course of the treatment consists of 4 weeks of daily treatment 5-7 times a week followed by 8 weeks of treatment 3 times a week. A single treatment takes approximately 30 minutes with or without interruptions.	5× weekly, 6 weeks	**BlueControl:** Subject device protocol is fewer treatments and shorter duration than predicate (30 treatments over 6 weeks vs 52 treatments over 12 weeks) **faceLITE:** Same
Treatment dose	18J/cm^2	72J/cm^2 ±9J/cm^2	18J/cm^2	**BlueControl:** Subject device dosage is significantly less than predicate **faceLITE:** Same
Cumulative dose	540J/cm^2	3744J/cm^2	540J/cm^2	**BlueControl:** Subject device dosage is significantly less than predicate **faceLITE:** Same

Description	Subject device handLITE (TN19S)	Predicate Philips BlueControl K171055	Predicate faceLITE LED mask K191629	Significant differences
Timers	Devices uses a timer and software to control treatment duration.	Yes - 30 minutes treatment per area after which device automatically switches off.	Devices uses a timer and software to control treatment duration.	**BlueControl:** Similar **faceLITE:** Same
Software controlled	Yes	Yes	Yes	**BlueControl:** Similar **faceLITE:** Same
Patient contacting materials	Transparent silicone inner glove surface and pocket. Nylon, spandex, and polyester yarn attachment strap.	Clear polycarbonate LED cover OEKO-TEX®-certified fabric device holder and straps	Transparent silicone inner mask surface. Nylon, spandex, and polyester yarn attachment strap.	**BlueControl:** Different LED housing materials (flexible silicone vs rigid polycarbonate). Both devices use materials listed in Attachment G of the FDA biocompatibility guidance issued 9/8/2023. **faceLITE:** Same

The subject device has been subjected to clinical performance testing to assess the safety and effectiveness of the device in treating contact dermatitis on the hand and wrist, as described below.

Electrical Safety Testing

handLITE was designed to meet applicable industry standards for electromagnetic compatibility (EMC) and electrical safety.

The device relies on standards identified for Medical Electrical Equipment which ensure that the product is safe and effective for its intended use regarding EMC and electrical safety.

handLITE has been tested and found to comply with the following applicable standards:

1. IEC 60601-1: 2005 + AMD1:2012 + AMD2:2020: Medical electrical equipment. General requirements for basic safety and essential performance
2. IEC 60601-1-2:2014+AMD1:2020. Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests for: Home Healthcare Environment
3. IEC TS 60601-4-2:2024 Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
4. IEC 60601-1-11:2015 + IEC 60601-1-11:2015/A1:2021 - 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.
5. IEC 60601-2-57:2011. Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
6. IEC 60601-2-83:2019. Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
7. IEC 62133-2:2017. Secondary Cells and Batteries Containing Alkaline or Other Non-Acid Electrolytes – Safety Requirements for Portable Sealed Secondary Cells, and for Batteries Made from Them, for Use in Portable Applications- Part 2: Lithium systems.

Non-Clinical Performance Testing

Eye Safety

In addition to the specific electrical safety standards cited above, handLITE has been tested to and complies with IEC 62471:2006, Photobiological safety of lamps and lamp systems.

Thermal safety

During normal operation with a treatment time of 10 minutes the change in skin temperature from baseline to the end of treatment is +3.4°C for handLITE, with a mean skin temperature of 36.4°C at the end of normal treatment. The glove surface, when in contact with the skin, increases from baseline by +1.8°C, with a mean surface temperature of 28.7°C at the end of normal treatment.

Light characteristics.

Results of testing by the sponsor verified the output characteristics of the device.

Usability/Human factors

The handLITE labeling was subject to label comprehension testing (IEC 62366-1:2015+A1:2020, Application of usability engineering to medical devices)

Nineteen subjects took part in the study, 6 male and 13 female. Twelve subjects (63%) were white, five subjects (26%) were Asian, one subject (5%) was Black or African American, and one subject (5%) was Native Hawaiian or Other Pacific Islander. Eight of the subjects (42%) identified as Hispanic or Latino. Nine subjects (47%) identified English as a second language. The mean age of the study group was 45.42 years of age, with a range of 27 to 61 years old. The average REALM (Rapid Estimate of Adult Literacy in Medicine) words incorrect was 8, with an average REALM score of 8, which represented 7^{th}-8^{th} grade. Two subjects presented with a REALM score of 4^{th}-6^{th} grade, ten with a 7^{th}-8^{th} grade score and the remaining seven had a score of high school.

All 19 subjects were able to complete all tasks by following the device's labeling, including instructions for use. Per the definitions of IEC 62366-1:2015+A1:2020, all tasks were performed within correct or normal use by all subjects.

Observations of tasks that were not completed exactly as specified in the labeling were within the bounds of normal use and did not pose additional hazards.

Clinical Performance Testing

A clinical study was undertaken to support the safety and effectiveness of the handLITE in the treatment of mild-to-moderate contact/irritant dermatitis of the hand.

The objective of the study was to assess the safety and effectiveness of the handLITE in reducing the signs and symptoms of contact dermatitis of the hand. The study included two groups with different treatment courses: Subjects in group 1 treated one hand at a time five times per week, for six weeks (12 weeks total, 30 treatments per hand); Subjects in group 2 treated one hand at a time, seven times per week, for eight weeks (16 weeks total, 56 treatments per hand). Each treatment session included a 10-minute treatment of the dorsal aspect (back) of the hand and a 10-minute treatment of the palmar aspect (palm). After the initial visit, patients conducted treatment sessions at home. The primary effectiveness endpoint was an improvement in the signs and symptoms of contact dermatitis, measured using the Scoring Atopic Dermatitis (SCORAD) index, with the untreated hand during the first treatment cycle used as a control.

Twenty-five subjects were enrolled in the study and twenty-three completed the full treatment course. Of the two subjects who did not complete the study, one was lost to follow-up after week 9 and the other became pregnant during the study and was discontinued at week 10 per the study's inclusion/exclusion criteria. Available data from both discontinued subjects were included in the evaluation of safety and efficacy.

The average subject age was 44 (range 24 to 63) and the group comprised 9 male and 16 female patients. All Fitzpatrick skin types were represented except type V. 22 subjects identified as white/Caucasian, 1 as Asian, 1 as Black, and 1 as American Indian or Alaska Native; 8 subjects identified as Hispanic or Latino.

There were no adverse events reported during the study. At the end of treatment, the mean improvement in grading of the signs and symptoms of dermatitis was 12.2 for the treated hand and 3.5 for the untreated (control) hand.

Subjects also completed a subjective assessment during the study. By the end of the study, 18 of 23 subjects (78%) reported an improvement in their dermatitis since starting the treatment, 15 of 23 subjects (65%) responded that their dermatitis was less itchy and scaly since starting the treatment, and 18 of 23 subjects responded that they were "not at all unhappy" about their contact dermatitis. All subjects also responded that the handLITE LED device was either "easy" or "extremely easy" to use.

The results of this study demonstrate that a 6-week course of 30 treatments using the handLITE LED device is effective in treating the signs and symptoms of contact dermatitis.

Conclusions

iSMART Developments LTD has demonstrated that the handLITE LED device has an equivalent intended use, the same generic classification, and the same basic principles and technologies as the predicate devices. Clinical performance testing demonstrates an improvement in the signs and symptoms of contact dermatitis and no safety concerns. Therefore, the handLITE LED device is substantially equivalent to the Philips Blue Control (K171055) and faceLITE LED mask (K191629).