July 24, 2026

iSMART Developments, Ltd.
% Steve Baker
Regulatory/Clinical Consultant
iSMART Consulting, LLC
3495 W Kamran Ridge Cv
South Jordan, Utah 84095

Re: K260598
Trade/Device Name: 5 Wavelength LED Facemask (TN2508)
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
Dated: February 23, 2026
Received: February 24, 2026

Dear Steve Baker:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.07.24 16:47:03 -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

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.	K260598

Please provide the device trade name(s).

5 Wavelength LED Facemask (TN2508)

Please provide your Indications for Use below.

The 5 wavelength LED facemask emits light in the red and near infrared (NIR) region of the light spectrum and is indicated for the treatment of full-face wrinkles.

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

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:	July 13th 2026
Device Trade Name:	5 wavelength LED facemask
Common Name:	Light Based Over the Counter Wrinkle Reduction
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810
Product Code:	OHS
Review Panel:	General & Plastic Surgery
Predicate Device:	K112362. Light Therapy System, Quasar Calypso C100.

Intended Use

The 5 Wavelength LED facemask emits light in the red and near-infrared (NIR) region of the light spectrum and is indicated for the treatment of full-face wrinkles.

Device Description

The 5 Wavelength LED Facemask (TN2508) consists of:

1. Flexible silicone facemask
2. Controller
3. Power supply and country specific adaptors
4. 4x silicone straps with Velcro fasteners
5. Carry bag
6. Silicone eye wear
7. User manual

The 5 Wavelength LED Facemask is a home use wearable LED phototherapy device that is worn on the face.

The device consists of a flexible silicone facemask that contains red (610nm, 630nm, and 660nm) and near-infrared (850nm and 1070nm) light emitting diodes, a controller that contains a

rechargeable Lithium Polymer battery, a power supply for charging the battery and 4 x silicone straps that attach the mask to the face. Hook and loop closures at the temples and chin allow the user to adjust the mask to fit the contours of their face. Silicone eyewear is provided and fits around the eye.

The controller contains a rechargeable Lithium-ion polymer battery. The controller switches the LEDs ON/OFF, controlling power to the mask.

The user switches the device ON to start a treatment, and the device turns OFF automatically. Each treatment is a 10-minute treatment. The controller uses a visible display comprising of 3 indicator-LEDs to show the user the battery charge status of the device.

The power supply is used to charge the Lithium polymer battery in the device and is connected to a suitable electrical outlet via a 2 or 3 pin plug. The power cable is connected to the controller by a standard USB-C connector.

Substantial Equivalence

The 5 Wavelength LED facemask device (TN2508) is substantially equivalent to the primary predicate device (Light Therapy System, Quasar Calypso C100. K112362).

Summary of Substantial Equivalence

The 5 Wavelength LED facemask device is predicated against the Light Therapy System, Quasar Calypso C100 (K112362) because both are LED phototherapy devices intended to emit light in the red and near-infrared regions of the light spectrum and indicated for the treatment of facial wrinkles.

Description	Subject device. 5 Wavelength LED Facemask Device TN2508	Light Therapy System, Quasar Calypso C100. K112362	Significant differences
Device Manufacturer	iSMART Developments LTD	Silver Bay, LLC (Quasar Bio-Technologies)	N/A
Device Trade Name	5 Wavelength LED Facemask Device TN2508	Light Therapy System, Quasar Calypso C100.	N/A
510(K) Number	K260598	K112362	N/A

Description	Subject device. 5 Wavelength LED Facemask Device TN2508	Light Therapy System, Quasar Calypso C100. K112362	Significant differences
Device Classification name	Light Based Over the Counter Wrinkle Reduction	Light Based Over the Counter Wrinkle Reduction	Same
Device Product Code	OHS	OHS	Same
Regulation Number	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.	Same
FDA Device Classification	Class II	Class II	Same
Use	Over the Counter	Over the Counter	Same
Intended use and Indications	The 5 Wavelength LED facemask emits light in the red and near-infrared (NIR) region of the light spectrum and is indicated for the treatment of full-face wrinkles.	The C100 is intended to emit energy in the red and IR region of the spectrum, specifically indicated for use in the treatment of periorbital wrinkles.	Similar
Intended Location of Use	Face	Face	Same
Energy Type	Light emitting diodes	Light emitting diodes	Same

Description	Subject device. 5 Wavelength LED Facemask Device TN2508	Light Therapy System, Quasar Calypso C100. K112362	Significant differences
Wavelengths	610nm ± 10 nm 630nm ± 10nm 660nm ± 10nm 850nm ± 10nm 1070nm ± 10nm	610nm 630nm 660nm 850nm	Different
Intensity	52.1mW/cm^2	65 mw /cm^2	Similar
Treatment time	600 seconds	180 seconds	Different
Treatment protocol	5× weekly, 6 weeks	5 times per week minimum	Different
Timers	Device uses a timer and software to control treatment duration.	ON/OFF no timer	Different
Software Controlled	Yes	No – manual ON/OFF	Different
Power Source	Lithium battery: 2200mAH, 5V output. Charging supply: 100-240Vac/50-60Hz. 0.25A	115 VAC Electrical outlet power supply	Different

Substantial Equivalency and Comparison of Technological Similarities & Differences

From the comparative table above, the 5 Wavelength LED facemask device demonstrates equivalence to the Light Therapy System, Quasar Calypso C100. K112362. The key similarities are:

i. The 5 Wavelength LED Facemask Device and the above referenced predicate Light Therapy System, Quasar Calypso C100 (K112362) device, are Over the Counter devices used to treat wrinkles as defined in 21 CFR § 878.4810.

ii. Both devices use red and near infrared light in the wavelengths of 610nm, 630nm, 660nm, and 850nm.

iii. Both devices deliver light energy at a similar intensity (50-65 mW/cm^2)

Differences between Subject device and Primary predicate

From the comparative table above, the following differences are noted:

Four wavelengths used by both devices are identical in respect to the centred wavelengths. In addition, the sponsor's device introduces the 1070nm wavelength of near infra-red light. Clinical data is included with this submission including an 8-week post-treatment follow up to demonstrate the safety and efficacy of the combination of wavelengths in the treatment of facial wrinkles.

Although both devices are intended to be used five times per week, the treatment duration of the two devices is not identical, with the subject device delivering light to the entire face for a period of 10 minutes, and the predicate delivering light to specific regions of the face for 3 minutes per area chosen by the user. The sponsor has submitted clinical data as part of this submission including an 8 week follow up evaluation post treatment to demonstrate that the device is safe and effective at the proposed treatment protocol.

The subject device utilizes basic software to control the treatment time, whereas the predicate device uses a simple ON/OFF switch. The subject device is powered by a Lithium battery, whereas the predicate uses a power adaptor. Where there are differences between the subject device and the predicate these have been addressed by Software and Electrical safety testing and non-clinical performance testing to the applicable standards.

Biocompatibility

The patient-contacting components of the 5-wavelength facemask include the inner surface of the face mask, the adjustable head straps, and the mandatory eyewear. All of the components are manufactured using the same medical grade silicone. Silicone is identified in the FDA Biocompatibility Guidance Attachment G, section B as a material that poses a very low biocompatibility risk when used in contact with intact skin for limited duration. Therefore, no further testing is required to support the biocompatibility of the TN2508 5 wavelength facemask device.

Electrical safety testing

The 5 Wavelength LED facemask device has been thoroughly evaluated for electrical safety and performance, and has been found to conform to the following standards:

- IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment. General requirements for basic safety and essential performance
- 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
- FCC CFR Title 47, Part 15, Subpart B-Section 15 Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: General requirements. Conducted & Radiated Emissions- Class B
- IEC 60601-11-2015+A1:2020 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.
- 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
- 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.
- IEC 60601-1-6:2010, AMD1:2013, AMD2:2020. Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62133-2:2012. 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

The 5 Wavelength LED facemask has been tested to and complies with IEC 62471:2006, Photobiological safety of lamps and lamp systems.

Thermal performance

During normal operation with a treatment time of 10 minutes, the average change in skin temperature from baseline to the end of treatment was +5.1°C. In a fault scenario where the device did not automatically end the treatment or the user chose to immediately repeat the treatment, there was a maximum increase of +5.7°C compared to baseline. The panel surface when in contact

with the skin increased from baseline by +7°C for the facemask after 10 minutes and by +7.4°C after 20 minutes

Light characteristics

Test results verified the output characteristics of the devices.

Usability/Human factors

The 5 Wavelength LED facemask device labelling was subject to label comprehension testing (EN 62366-1:2015. Application of usability engineering to medical devices).

Nineteen subjects took part in the study, 7 male and 12 females. The average age of the study group was 44 (range 29-61). The average number of REALM words incorrect was 7, with an average REALM score of 58, which represented 7th-8th grade. Two subjects presented with a REALM score of 4th-6th grade, 9 with a 7th-8th grade score and the remaining 8 had a score of "high school"

In terms of ethnicity, 13 subjects were White, 5 were Asian and 1 black or African American. Seven subjects were White Hispanic or Latino. Nine subjects identified English as a second language.

The results showed no definitive user error (failure to carry out a task correctly) or abnormal use (violation, conscious disregard for the contraindications, warnings etc.)

No new use errors, hazards, hazardous situations, or hazard-related use scenarios were discovered during testing. Further improvement of the labeling as it relates to safety and self-selection was deemed unnecessary and there were no suggested revisions to the version of the user manual or box packaging tested.

Clinical Performance

To support the device intended use, a clinical study of 24 subjects was conducted per 21 CFR 50, 21 CFR 56, 21 CFR 812 and in accordance with Good Clinical Practices to assess the efficacy of red and near infra-red wavelengths of light in treating the visible signs of skin ageing (facial wrinkles).

Visible signs of skin aging (facial wrinkles) were measured using the Scientific Assessment Scale of Skin Quality SASSQ (Eiben-Nielson & Kerscher, 2021). The duration of the study was 14 weeks. There were no adverse events reported during the study and treatment period, and no reported incidents up to 8 weeks post treatment.

Twenty-four subjects were enrolled in and completed the study. Data from all subjects was included for analysis. One subject was male and 23 were females. The average subject age was 48

years (range 30-65). All Fitzpatrick skin types were represented. Seventeen (n=17) subjects identified as Caucasian (white), two (n=2) as Black/African American, two (n=2) as Asian, two (n=2) as Asian/Indian, and one (n=1) as Native American Indian/Alaskan native. Five subjects identified as of Hispanic ethnicity.

The study was an open-label, non-randomized study. At the end of the study photographic images were collated, masked, and randomized, and assessed by blinded independent physicians.

Each subject used the device at home 5 times per week for 12 weeks. Each treatment session consisted of a 10-minute treatment of the face. During treatment, the device delivered a combination of red (610nm, 630nm, 660nm) and near infra-red (850nm, and 1070nm) light at an intensity of 52.1 mW/cm^2.

Subjects were assessed in the clinic at Baseline, Week 9, and Week 14. Research staff contacted the subjects 1 week and 4 weeks after baseline assessment to confirm compliance with study procedures and to answer questions the subject may have. The assessments at Week 9 and Week 14 consisted of a physician assessment of facial ageing using SASSQ, a subjective assessment of treatment response, digital photography of the subject, and reporting of any adverse events.

An additional follow-up by telephone was completed 8 weeks after the end of the study (week 20) to review any potential incidents post treatment. At the end of the study, images were collated and masked for review by two additional physicians.

At Baseline, the mean wrinkle grade for the study group was 2.1 (moderate), with a range of 1-4. At Week 14, the mean grade score was 1.4, representing a reduction of 0.7 of a grade. Although the mean result did not achieve the primary endpoint of $\geq$ 1 grade improvement, 19 subjects (79%) were judged to have improved by $\geq$ 1 grade.

At Weeks 9 and 14, subjects were also questioned on treatment outcomes using a 5-point Likert scale questionnaire with the following options: no improvement (0%), little improvement (>0% to 30%), some improvement (30% to 50%), improved (50% to 75%) and greatly improved (>75%).

Seventy-one percent of subjects reported some improvement or greater in their facial wrinkles.

Statement of Substantial Equivalence:

513(i) of the FD&C Act (21 U.S.C. 360c(i)) states that for substantial equivalence a proposed device is required to have the same intended use and similar technological characteristics as the predicate device. Where there are differences in technological characteristics, these can be negated by appropriate clinical or scientific data demonstrating that the proposed device is as safe and effective as the predicate device, and that the proposed device does not raise any different questions of safety and effectiveness than the predicate device for the same intended use.

iSMART Developments LTD has demonstrated that the 5 Wavelength LED facemask device has the same generic classification, and the same basic principles and technologies as the predicate device. Both devices utilize red and NIR wavelengths of light with similar power densities

iSMART Developments LTD has conducted both clinical and non-clinical performance testing applicable and has determined that the 5 Wavelength LED facemask device is substantially equivalent to the Light Therapy System, Quasar Calypso C100.

The 5 Wavelength LED facemask device TN2508 is as safe, as effective, and performs as well as or better than the legally marketed predicated device Light Therapy System, Quasar Calypso C100.

July 13th 2026.