June 3, 2026

The Beauty Tech Group, Ltd.
Harriet Cavanagh
Regulatory Compliance Specialist
Glasshouse, Suite 3f1, Congleton Rd.
Macclesfield, SK10 4ZE
United Kingdom

Re: K260715
Trade/Device Name: CurrentBody Skin LED Multi Light Therapy Mask (MK-110D)
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, ILY
Dated: March 5, 2026
Received: March 5, 2026

Dear Harriet Cavanagh:

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: 2026.06.03 16:19:19 -04'00'

Tanisha Hithe, MS, MHS
Assistant Director
Division of General Surgery Devices
Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K260715

Device Name
CurrentBody Skin LED Multi Light Therapy Mask, Model: MK-110D

Indications for Use *(Describe)*
The CurrentBody Skin™ LED Multi Light Therapy Mask is an over-the-counter, non-invasive light therapy device.

The CurrentBody Skin™ LED Multi Light Therapy Mask delivers visible and near-infrared (NIR) light to the face via non-coherent light-emitting diodes (LEDs). The mask provides four selectable treatment modes:

Mode 1 (including red (633nm), NIR (830nm & 1072nm)) is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

Mode 2 (including blue (415nm) & red (633nm)) is intended for the treatment of mild to moderate inflammatory acne.

Mode 3 (including yellow (590nm) & NIR (830nm)) is intended for the treatment of full face wrinkles.

The device is intended for use on Fitzpatrick skin types I–IV.

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.**

**The Beauty Tech Group**
**Traditional 510(k)**
**For CurrentBody Skin LED Multi Light Therapy Mask**
**510(k) Summary**

K260715

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

**Submitter's Name:**

The Beauty Tech Group Ltd

**Submitter's Address:**

Suite 3F1, Glasshouse, Congleton Road, Macclesfield, Cheshire, SK10 4TG, United Kingdom

**Establishment Registration Number:**

3014737458

**Contact Person:** Miss Harriet Cavanagh

**Telephone:** +447961241663

**Email:** harriet.cavanagh@thebeautytechgroup.com

**Date Prepared:** 21 MAY 2026

**The Beauty Tech Group**
**Traditional 510(k)**
**For CurrentBody Skin LED Multi Light Therapy Mask**

**Device Classification Information:**

| Regulation | Device Name | Device Classification | Product Code | Classification Panel |
|---|---|---|---|---|
| 21 CFR 878.4810 | CurrentBody Skin LED Multi Light Therapy Mask | II | OHS, OLP, ILY | General & Plastic Surgery |

**Device Trade Name:** CurrentBody Skin LED Multi Light Therapy Mask Model: MK-110D.

**Device Common Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology

**Device Description:**

The CurrentBody Skin LED Multi Light Therapy Mask is an over-the-counter (OTC), non-invasive, wearable light therapy device.

The device delivers multiple visible (red (633 ± 1.5nm), blue (415nm ± 1.5nm), yellow (590nm ± 1.5 nm), green (532nm ± 1.5nm)) and near-infrared (NIR) (830nm ± 1.5nm & 1072nm ± 8nm) light to intact external facial skin via non-coherent light-emitting diodes (LEDs).

The CurrentBody Skin LED Multi Light Therapy Mask provides four selectable treatment modes:

- Mode 1 (including red (633nm), NIR (830nm & 1072nm)): To provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
- Mode 2 (including blue (415nm) & red (633nm)): Treatment of mild to moderate inflammatory acne.
- Mode 3 (including yellow (590nm) & NIR (830nm)): Treatment of full face wrinkles
- Mode 4 (including green (532nm) is provided for user comfort and relaxation purposes only.

The CurrentBody Skin LED Multi Light Therapy Mask is powered by a Lithium-Ion rechargeable battery. Accessories include: USB-C charging cable, eye-inserts, adjustable Velcro straps, storage bag and instruction manual.

**Intended Purpose/ Indications for Use:**

The CurrentBody Skin™ LED Multi Light Therapy Mask is an over-the-counter, non-invasive light therapy device.

The CurrentBody Skin™ LED Multi Light Therapy Mask delivers visible and near-infrared (NIR) light to the face via non-coherent light-emitting diodes (LEDs). The mask provides four selectable treatment modes:

- Mode 1 (including red (633nm), NIR (830nm & 1072nm)) is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
- Mode 2 (including blue (415nm) & red (633nm)) is intended for the treatment of mild to moderate inflammatory acne.
- Mode 3 (including yellow (590nm) & NIR (830nm)) is intended for the treatment of full face wrinkles

The device is intended for use on Fitzpatrick skin types I–IV.

**Summary of Substantial Equivalence:**

**Primary Predicate:**

The following predicate device has been selected in order for the CurrentBody Skin LED Multi Light Therapy Mask to claim equivalence to. The primary predicate is as follows:

- K251588: LED Light Therapy Mask/Model (FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910)
- Product code: OHS, OLP

Compared with the primary predicate device (K251588), the subject device is very similar in design principle, intended use, indications for use, operating principles, performance specifications and the applicable testing standards.

Both devices are non-invasive LED light therapy masks intended for dermatological and cosmetic facial treatments for over-the-counter (OTC) lay use that deliver light energy to the facial skin surface for therapeutic benefit.

Any minor difference in LED configuration, light output parameters or software control do not alter the fundamental technology or raise new questions of safety or effectiveness. Any technical difference have been duly justified with legally marketed reference devices or other appropriate justifications.

**Secondary Predicate Device:**

The following reference device has been selected in order to support the CurrentBody Skin LED Multi Light Therapy Mask application for substantial equivalence to. Secondary predicate device is as follows:

- K242593: CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (MK-90C, MK-90M, MK66RB-F, MK-90N)
- Product code: OHS, OLP

Compared with the secondary predicate device (K242593), the subject device is highly similar in design principle, technological characteristics, intended use, indications for use, operating modes and the applicable standards.

Any differences in LED wavelength combinations, light intensity, or treatment protocols do not introduce new safety or effectiveness concerns and have been adequately addressed through verification testing and comparison to legally marketed devices.

**Tertiary Predicate Device:**

The following predicate device has been selected in order to support the CurrentBody Skin LED Multi Light Therapy Mask application for substantial equivalence to. The tertiary predicate device is as follows:

- K260129: Lumaflex Panel / Model (ZLD-05, ZLD-05A, ZLD-05APro)
- Product code: OLI, OHS, ILY

The tertiary predicate device (K260129) is referenced to support two specific aspects of the subject device: (1) the ILY therapeutic heating intended purpose (21 CFR 890.5500), and (2) the technological characteristic of near-infrared LED emission at 1072nm by comparison to the tertiary predicate's 1064nm.

The tertiary predicate device is cleared under the ILY product code (21 CFR 890.5500) for topical heating using near-infrared LED emission at 1064nm for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The subject device's Mode 1 delivers red (633nm) and near-infrared (830nm & 1072nm) LEDs for the same therapeutic heating indication. The subject device therefore adopts the ILY intended purpose from the tertiary predicate, supported by comparable irradiance levels and treatment durations.

The subject device employs LEDs at 1072nm, which differs from the tertiary predicate's 1064nm by only 8nm. Both wavelengths fall within the same near-infrared optical window and the narrow spectral difference does not alter the mechanism of energy delivery, tissue interaction, or safety profile.

The subject device does not adopt the OLI product code or 21 CFR 878.5400 intended purpose from the tertiary predicate for non-invasive dermatological aesthetic treatment for reduction of circumference of hips, waist, and thighs. The subject device is not seeking clearance under this regulation and does not intend to make claims associated with the OLI indication.

Any differences in device form factor (mask vs panel), anatomical application area, LED count, or treatment mode configurations do not alter the fundamental near-infrared LED technology or raise new questions of safety or effectiveness with respect to the ILY therapeutic heating indication or the technological characteristic of 1072nm emission. Accordingly, the subject device is considered substantially equivalent to K260129 with respect to the ILY therapeutic heating indication and the technological characteristic of 1072nm near-infrared LED emission.

**The Beauty Tech Group**
**Traditional 510(k)**
**For CurrentBody Skin LED Multi Light Therapy Mask**

**Technological Characteristics and Substantial Equivalence Table:**

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| **Company Name** | The Beauty Tech Group | Shenzhen Fittop Health Technology Co.,Ltd. | Shenzhen Kaiyan Medical Equipment Co., Ltd | Shenzhen Kaiyan Medical Equipment Co., Ltd | N/A | N/A |
| **Trade Name** | CurrentBody Skin LED Multi Light Therapy Mask | LED Light Therapy Mask | CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask | Lumaflex Panel | N/A | N/A |
| **Model** | Model: MK-110D | Model: FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910 | Model: MK-90C, MK-90M, MK66RB-F, MK-90N | Model: Model ZLD-05, ZLD-05A & ZLD-05APro | N/A | N/A |
| **510(k) Number** | K260715 | K251588 | K242593 | K260129 | N/A | N/A |
| **Regulation Number** | 21 CFR 878.4810<br>21 CFR 890.5500 | 21 CFR 878.4810 | 21 CFR 878.4810 | 21 CFR 878.4810<br>21 CFR 890.5500<br>21 CFR 878.5400 | Similar | The tertiary Predicate (K260129; product codes OLI, ILY & OHS; 21 CFR 878.4810,<br>21 CFR 890.5500<br>& 21 CFR 878.5400) utilises 21 CFR 878.5400 for Mode 1 of Model ZLD-05.<br><br>The subject device is not seeking clearance under 21 CFR 878.5400 and does not intended to adopt the associated intended purpose of the OLI product code.<br><br>Any minor differences do not raise any new questions in regard to safety and effectiveness. |
| **Product Code** | OHS, OLP, ILY | OHS, OLP, ILY | OHS, OLP | OLI, OHS, ILY | Similar | The primary predicate (K251588; product codes |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | OHS, OLP, ILY) and the secondary predicate (K242593; product codes OHS, OLP) support the intended use, device design, technological characteristics, and dermatological facial treatment indications of the subject device.<br><br>The tertiary predicate device (K260129; product codes OLI, OHS, ILY) is referenced to support two aspects of the subject device:<br>1. the ILY product code (Therapeutic Heating; 21 CFR 890.5500) intended purpose, as the tertiary predicate is cleared for topical heating using near-infrared LED emission at 1064 nm for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting the relaxation of muscle tissue, and temporarily increasing local blood circulation; and |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | 2. the technological characteristic of near-infrared LED emission in the 1064 - 1072nm band, demonstrating regulatory precedent for its safe topical application to external skin in a lay-user population.<br><br>The subject device employs LEDs at 1072nm, which differs from the tertiary predicate's 1064nm by only 8nm. Both wavelengths fall within the same near-infrared optical window and are governed by the same photobiological absorption and scattering mechanisms in human tissue. This narrow spectral separation does not alter the mechanism of action, tissue interaction, or safety profile.<br><br>The tertiary predicate is not used to support the OLI product code or 21 CFR 878.5400 intended purpose for non-invasive dermatological aesthetic treatment for circumference reduction; |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | the subject device does not seek clearance under this regulation or adopt this indication. |
| **Common Name** | Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Therapeutic Heating(ILY) | Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared, Therapeutic Heating(ILY) | Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne (OLP) | Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Therapeutic Heating(ILY) | Same | N/A |
| **Classification** | II | II | II | II | Same | N/A |
| **Indications for Use/ Intended Use** | The CurrentBody Skin™ LED Multi Light Therapy Mask is an over-the-counter, non-invasive light therapy device.<br><br>The CurrentBody Skin™ LED Multi Light Therapy Mask delivers visible and near-infrared (NIR) light to the face via non-coherent light-emitting diodes (LEDs). The mask provides four selectable treatment modes:<br>• Mode 1 (including red (633nm), NIR (830nm & 1072nm)) is intended to provide topical heating for the purpose of | The LED Light Therapy Mask is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.<br><br>**FCM902, FCM905, FCM906, FCM908**:<br>a. Red light: Treatment of full-face wrinkles.<br><br>b. Blue+Infrared light: Treatment of mild to moderate inflammatory acne.<br><br>c. Yellow+Infrared light: Treatment of full-face wrinkles.<br><br>**11-001-RBMASK**: | **For MK-90C**:<br><br>The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: Mk-90C) is an over the counter device, specifically indicated to treat mild to moderate acne vulgaris of the face and use in the treatment of full-face wrinkles.<br><br>**For MK-90M**:<br><br>The CurrentBody™ LED 4in 1 Zone Facial Mapping Mask(Models: MK-90M is an over the counter device intended for the use in the treatment of full face wrinkles. | **For Model ZLD-05:**<br><br>- Mode 1: The Lumaflex Panel is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.<br><br>- Mode 2: The Lumaflex Panel is intended for use in the treatment of full-face wrinkles.<br><br>- Mode 3: The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor | Similar | The CurrentBody Skin LED Multi Light Therapy Mask is an over-the-counter (OTC), non-invasive LED light therapy device intended for the treatment of facial wrinkles, mild to moderate inflammatory acne, and topical heating for the temporary relief of minor muscle and joint pain.<br><br>The wrinkle and acne treatment indications are the same as the primary predicate device (K251588) and the secondary predicate device (K242593), which are OTC LED facial masks indicated for treatment of full-face wrinkles and/or |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.<br>• Mode 2 (including blue (415nm) & red (633nm)) is intended for the treatment of mild to moderate inflammatory acne.<br>• Mode 3 (including yellow (590nm) & NIR (830nm)) is intended for the treatment of full face wrinkles<br><br>The device is intended for use on Fitzpatrick skin types I–IV. | a. Red+Infrared light: Treatment of full-face wrinkles.<br><br>b. Blue light: Treatment of mild to moderate inflammatory acne.<br><br>**FCM910**:<br><br>a. Red+Infrared light: Treatment of full-face wrinkles.<br><br>b. Blue light: Treatment of mild to moderate inflammatory acne.<br><br>c. Yellow+Infrared light: Treatment of full-face wrinkles. | **For MK66RB-F**:<br><br>The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK66RB-F) is an over the counter device, specifically indicated to treat mild to moderate acne vulgaris.<br><br>**For MK-90N**:<br><br>The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask(Models: MK-90N) is an over the counter device, is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles. | muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.<br><br>**For Model ZLD-05A:**<br><br>- Mode 1: The Lumaflex Panel is intended for use in the treatment of full-face wrinkles.<br><br>- Mode 2: The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.<br><br>**For Model ZLD-05APro:**<br><br>- Mode 1: The Lumaflex Panel is indicated for use as a non-invasive dermatological aesthetic | | mild to moderate inflammatory acne.<br><br>The topical heating indication (ILY; 21 CFR 890.5500) is the same as the tertiary predicate device (K260129, Lumaflex Panel), which is cleared for topical heating using near-infrared LED emission at 1064nm for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.<br><br>The subject device's Mode 1 delivers 1072nm LEDs for this same therapeutic heating indication. The 1072nm emission is within 8nm of the tertiary predicate's 1064nm; the 8nm spectral shift does not introduce new questions of safety or effectiveness.<br><br>All devices are intended for use by lay users and deliver non-coherent light |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | treatment for the reduction of circumference of hips, waist, and thighs.<br><br>- Mode 2: The Lumaflex Panel is intended to deliver heat in the near infra-red spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis, and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.<br><br>- Model 3: The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. | | energy to intact facial skin for dermatological and therapeutic purposes. Total radiant exposure, irradiance, and thermal output of the subject device are comparable to or lower than those of the predicate devices.<br><br>Green light (532 nm) is included for user comfort and relaxation only and is not associated with therapeutic claims, and therefore does not modify the intended use nor is it included.<br><br>Accordingly, the subject device has the same intended use as the primary and secondary predicate devices for wrinkle and acne treatment, and the same intended use as the tertiary predicate device for therapeutic heating. Any differences in wavelength combinations or LED configuration do not alter the fundamental technology or raise new questions of safety or effectiveness. |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | The subject device is therefore substantially equivalent with respect to intended use. |
| **Intended Location for Use** | Face | Face | Face | Face and Body | Same (see **note**) | **Note**: The subject device is intended for application to the external facial skin, consistent with the primary predicate (K251588) and secondary predicate (K242593) devices, which are also indicated for full-face dermatological treatment. Both the subject, primary predicate and secondary predicate devices are mask-style LED light therapy systems designed for topical application to intact facial skin. The tertiary predicate device (K260129) is indicated for face and body application<br><br>The tertiary predicate's broader anatomical indication does not alter the subject device's intended location of use, as the subject device applies the therapeutic heating indication solely to facial skin. |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | Treatment with the subject device is limited to intact external facial skin only. |
| **Intended User** | Lay user (Male & Female) | Lay user (Male & Female) | Lay user (Male & Female) | Lay user (Male & Female) | Same | N/A |
| **OTC or Prescription Use** | OTC | OTC | OTC | OTC | Same | N/A |
| **Energy Type** | Light emitting diodes | Light emitting diodes | Light emitting diodes | Light emitting diodes | Same | N/A |
| **Power Supply** | Input: 100 - 240V ~ 50/60Hz<br><br>Output: DC 5V<br><br>Lithium battery<br><br>3.7Vdc, 5000mAh, 18.5Wh | Input: 100 - 240V ~ 50/60Hz<br><br>Li-ion Polymer Battery **(FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK)**: 2850mAh<br><br>Li-ion Polymer Battery (**FCM910**): 1000mAh | Input: 100 - 240V, 50/60Hz<br><br>Output: DC 5V, 2A<br><br>**MK-90C and MK-90N**: 3.7Vdc, 5200mAh, 19.24Wh Lithium battery<br><br>**MK66RB-F and MK-90M**: 3.7Vdc, 2600mAh, 9.62Wh Lithium battery | Not publicly available | Similar | The power supply for the subject device is slightly different from that of the predicate device.<br><br>Secondary predicate device has a very similar power supply to the subject device.<br><br>The lithium battery of the subject device has passed IEC 62133-2 test and the power adapter has been assessed for electrical safety along with the main unit.<br><br>Any minor differences do not raise any new questions in regard to safety and effectiveness. |
| **Number of LEDs** | • 415nm: n=110<br>• 532nm: n=110<br>• 590nm: n=110<br>• 633nm: n=110<br>• 830nm: n=110 | Not publicly available | • 415nm: n=90<br>• 590nm: n=90<br>• 633nm: n=90<br>• 830nm: n=90 | • Model ZLD-05: n=45<br>• Model ZLD-05A: n=45<br>• Model ZLD-05APro: n=50 | Different | The subject device incorporates a different total number of LEDs compared secondary |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | • 1072nm: n=16 | | | | | predicate and tertiary predicate device.<br><br>However, LED quantity alone does not determine safety or effectiveness.<br><br>The therapeutic output of the device is governed by irradiance (mW/cm²), radiant exposure (J/cm²), wavelength, treatment duration, and spatial distribution of optical energy across the treatment surface.<br><br>Although the subject device utilises 110 LEDs for certain wavelengths and 16 LEDs for 1072nm, while the secondary predicate device utilises 90 LEDs per wavelength, these differences reflect design configuration and mask geometry rather than a change in fundamental technology or therapeutic principle.<br><br>Notably, the 16 LEDs at 1072nm in the subject device deliver an irradiance of 7mW/cm², which is within the performance range of |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | near-infrared modes in the tertiary predicate device (K260129) that utilises 1064nm LEDs across 45–50 LEDs per model variant.<br><br>The reduced LED count for the 1072nm wavelength is appropriate given the supplementary role of 1072nm within Mode 1 and does not compromise the therapeutic output or safety profile of the device.<br><br>Accordingly, differences in LED count represent design variations and do not raise new questions of safety or effectiveness. |
| **Wavelength** | • 415nm ± 1.5nm blue light<br>• 532nm ± 1.5nm green light<br>• 590nm ± 1.5 nm yellow light<br>• 633 ± 1.5nm visible red light<br>• 830nm ± 1.5nm non-visible red light<br>• 1072nm ± 8nm non-visible red light | • 415nm ± 5nm blue light<br>• 520nm ± 5nm green light<br>• 590nm ± 5nm yellow light<br>• 630nm ± 5nm visible red light<br>• 880nm ± 5nm non-visible red light | • 415nm<br>• 590nm<br>• 633nm<br>• 830nm | • 630nm<br>• 660nm<br>• 810nm<br>• 850nm<br>• 904nm<br>• 1064nm | Similar | The subject device utilises visible wavelengths (415nm, 532nm, 590nm, 633nm) and near-infrared wavelengths (830nm and 1072nm) delivered via non-coherent LEDs. The visible and 830nm near-infrared wavelengths align directly with those used in the primary predicate (K251588) and secondary predicate (K242593) devices for wrinkle and acne treatment. |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | The primary predicate utilises 415nm, 520nm, 590nm, 630nm, and 880nm; the secondary predicate utilises 415nm, 590nm, 633nm, and 830nm. The inclusion of 1072 nm in the subject device represents a supplemental near-infrared wavelength within the same non-coherent LED optical energy category, employed in Mode 1 for the ILY therapeutic heating intended purpose (21 CFR 890.5500). The tertiary predicate device (K260129, Lumaflex Panel Model ZLD-05APro) employs LEDs at 1064nm for the same therapeutic heating indication, establishing clear regulatory precedent for the use of near-infrared wavelengths in the 1060–1075nm region for topical application to external skin. The 8nm difference between the subject device's 1072nm and the tertiary predicate's 1064nm is spectroscopically negligible: both |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | wavelengths occupy the same near-infrared optical window, interact with the same tissue chromophores (principally water and deoxyhaemoglobin), and exhibit equivalent optical penetration depth and scattering behaviour in human skin.<br><br>Accordingly, the 1072nm emission of the subject device is functionally equivalent to the 1064nm emission of the tertiary predicate and does not introduce new questions of safety or effectiveness.<br><br>All wavelengths are delivered to intact external facial skin under controlled irradiance and exposure conditions. |
| **Treatment Modes** | **Mode 1**:<br><br>• Red (633nm), NIR (830nm & 1072nm)<br><br>**Mode 2**:<br>• Blue (415nm) & red (633nm)<br><br>**Mode 3**: | **FCM902, FCM905, FCM906, FCM908:**<br><br>**1)** Red (630nm)<br>**2)** Yellow + NIR (590nm+880nm)<br>**3)** Green (520nm)<br>**4)** Blue + NIR (415nm+880nm)<br><br>**11-001-RBMASK:** | **MK-90C**:<br><br>Mode 1: Red + Infrared (633nm+830nm)<br>Mode 2: Blue + Red (415nm+633nm)<br>Mode 3: Yellow + Infrared (590nm+830nm)<br><br>**MK-90M**:<br>Mode: Red + Infrared | **Model ZLD-05:**<br><br>Mode 1: Red (630nm) & NIR (850nm)<br>Mode 2: Red (630nm) & NIR (850nm)<br><br>**Model ZLD-05A:**<br><br>Mode1: Red (630nm) & NIR (850nm) | Similar | The subject device provides four selectable treatment modes utilising combinations of visible and near-infrared (NIR) wavelengths delivered via non-coherent LEDs. These include red (633nm), blue (415nm), yellow (590nm), green (532nm), and near- |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | • Yellow (590nm) & NIR (830nm)<br><br>**Mode 4**:<br><br>• Green (532nm) | **1)** Blue (415nm)<br>**2)** Red + NIR (630nm+880nm)<br><br>**FCM910:**<br><br>**1)** Red + NIR (630nm+880nm)<br>**2)** Yellow + NIR (590nm+880nm)<br>**3)** Green (520nm)<br>**4)** Blue (415nm) | (633nm+830nm)<br><br>**MK66RB-F**:<br><br>Mode: Red + Blue (633nm +415nm)<br><br>**MK-90N**:<br><br>Mode: Yellow + Infrared (590nm+830nm) | Mode 2: Red (630nm) & NIR (850nm)<br>Mode 3: Red (630nm) & NIR (850nm)<br><br>**Model ZLD-05APro:**<br><br>Mode 1: Red (630nm & 660nm) & NIR (810nm, 850nm, 904nm & 1064nm)<br>Mode 2: Red (630nm & 660nm) & NIR (810nm, 850nm, 904nm & 1064nm) | | infrared (830nm and 1072nm) wavelengths.<br><br>The primary predicate device (K251588) and secondary predicate (K242593) similarly provide multiple selectable treatment modes incorporating combinations of red, blue, yellow, green, and near-infrared wavelengths for treatment of facial wrinkles and mild to moderate inflammatory acne.<br><br>Whilst the exact combinations and number of selectable modes differ slightly among devices, these differences reflect variations in software configuration and user interface rather than changes in fundamental technology or intended therapeutic application. All devices deliver non-coherent LED optical energy to intact external facial skin for wrinkle treatment, acne management, and/or therapeutic heating. |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | The wavelength combinations used in the subject device align with those employed by the predicate devices for similar dermatological indications.<br><br>Mode 1 of the subject device includes red (633nm) and NIR (830nm & 1072nm) and is intended for topical heating (ILY; 21 CFR 890.5500). This therapeutic heating indication is the same as that of the tertiary predicate device (K260129), which has received clearance for modes incorporating 1064 nm LEDs (Model ZLD-05APro) for topical heating and temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting the relaxation of muscle tissue, and temporarily increasing local blood circulation. The subject device's 1072nm emission is within 8nm of the tertiary predicate's 1064nm, and this narrow spectral difference does not alter the mechanism of |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | energy delivery, tissue interaction, or intended therapeutic objective. The red and 830nm components of Mode 1 directly align with predicate configurations (for example red + infrared modes in both the primary and secondary predicates).<br><br>Modes incorporating blue light (415nm) for acne treatment and red/yellow/infrared combinations for wrinkle treatment are consistent with the primary and secondary predicate devices.<br><br>The green light (532nm) mode is included for user comfort and relaxation only and is not associated with therapeutic claims, and therefore does not impact the intended use.<br><br>Accordingly, the treatment modes of the subject device are considered technologically similar to those of the predicate devices and do not raise |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | new questions of safety or effectiveness. |
| **LED Power (Irradiance)** | **Mode 1:**<br>• 633nm: 18mW/cm$^2$<br>• 830nm: 13mW/cm$^2$<br>• 1072nm: 7mW/cm$^2$<br><br>**Mode 2:**<br>• 415nm: 18mW/cm$^2$<br>• 633nm: 26mW/cm$^2$<br><br>**Mode 3**:<br>• 590nm: 15mW/cm$^2$<br>• 830nm: 13mW/cm$^2$<br><br>**Mode 4**:<br>• 532nm: 5mW/cm$^2$ | **415nm**:<br>• Low: 15mW/cm$^2$<br>• Medium: 20mW/cm$^2$<br>• High: 25mW/cm$^2$<br><br>**520nm**:<br>• Low: 3mW/cm$^2$<br>• Medium: 4mW/cm$^2$<br>• High: 5mW/cm$^2$<br><br>**590nm**:<br>• Low: 5mW/cm$^2$<br>• Medium: 7mW/cm$^2$<br>• High: 10mW/cm$^2$<br><br>**630nm**:<br>• Low: 15mW/cm$^2$<br>• Medium: 20mW/cm$^2$<br>• High: 25mW/cm$^2$<br><br>**880nm**:<br>• 10mW/cm$^2$ | • 415nm: 25±5mW/cm$^2$<br>• 590nm: 15±5mW/cm$^2$<br>• 633nm: 20±5mW/cm$^2$<br>• 830nm: 10±5mW/cm$^2$ | **Model ZLD-05:**<br><br>• Mode 1: 4.2mW/cm$^2$<br>• Mode 2: 30mW/cm$^2$<br>• Mode 3: 65mW/cm$^2$<br><br>**Model ZLD-05A:**<br><br>• Mode 1: 30mW/cm$^2$<br>• Mode 2: 65mW/cm$^2$<br><br>**Model ZLD-05APro:**<br><br>• Mode 1: 4.2mW/cm$^2$<br>• Mode 2: 20mW/cm$^2$<br>• Mode 3: 65mmW/cm$^2$ | Similar | The subject device delivers visible and near-infrared light via non-coherent LEDs at irradiance levels that are comparable to those of the predicate devices.<br><br>The exact irradiance values differ slightly across wavelengths and treatment modes, these variations fall within the performance range established by the predicate devices.<br><br>For red, blue, yellow, and 830nm near-infrared wavelengths, the subject device operates at irradiance levels that are similar to or lower than those of the primary predicate (K251588) and secondary predicate (K242593) devices.<br><br>The primary predicate delivers 415nm at 15–25 mW/cm², 630nm at 15–25mW/cm², and 880nm at 10mW/cm²; the secondary predicate delivers 415nm at 25±5mW/cm², 633nm at |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | 20±5mW/cm², and 830nm at 10±5mW/cm². The subject device's corresponding values (415nm at 18mW/cm², 633nm at 18–26mW/cm², 830nm at 13mW/cm²) fall within these ranges.<br><br>The 1072nm LEDs in the subject device deliver 7mW/cm², which is within the irradiance range of near-infrared modes in the tertiary predicate device (K260129). The tertiary predicate device operates at irradiance levels ranging from 4.2mW/cm² to 65mW/cm² across its modes using 1064nm LEDs. The subject device's 1072nm irradiance of 7mW/cm² is at the lower end of this range, and the 8nm wavelength difference does not alter the photobiological interaction with tissue at these power densities.<br><br>The primary predicate delivers 532nm at 5mW/cm$^2$ which is identical to the subject device. |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | The subject device has been evaluated for compliance with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-83, and IEC 62471. Testing confirms that the irradiance levels used do not introduce increased thermal risk, photobiological hazard, or other safety concerns relative to the predicate devices.<br><br>Accordingly, the differences in LED irradiance values represent minor performance variations within the same technological category and do not alter the intended use, mechanism of energy delivery, or raise new questions of safety or effectiveness. |
| **Treatment Time** | All modes: 10 minutes, 3-5 times per week | **FCM902:**<br><br>• Red: 3 minutes<br>• Yellow + NIR: 3 minutes<br>• Green: 3 minutes<br>• Blue + NIR: 3 minutes<br>• Auto-Mode: 8 minutes | All modes: 10 minutes<br><br>Wrinkles: up to 5 times per week<br>Acne: up to 4 times per week | **For Model ZLD-05:**<br><br>• Mode 1: 30 minutes<br>• Mode 2: 10 minutes<br>• Mode 3: 15 minutes<br><br>**Model ZLD-05A:**<br><br>• Mode 1: 10 minutes | Similar | The treatment durations of the subject device and the predicate devices are comparable, although not identical.<br><br>Treatment time is one of several parameters that contribute to achieving the intended therapeutic |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | **FCM905, FCM906, FCM908:**<br>• Red: 3 minutes<br>• Yellow + NIR: 3 minutes<br>• Green: 3 minutes<br>• Blue + NIR: 3 minutes<br>**11-001-RBMASK:**<br>• Blue: 10 minutes<br>• Red + NIR: 10 minutes<br>**FCM910**:<br>• Yellow + NIR: 3 minutes<br>• Red + NIR: 3 minutes<br>• Green: 3 minutes<br>• Blue: 3 minutes<br>• Auto-Mode: 8 minutes | | • Mode 2: 15 minutes<br>**Model ZLD-05APro:**<br>• Mode1: 30 minutes<br>• Mode 2: 15 minutes<br>• Mode 3: 10 minutes | | effect, in conjunction with irradiance, wavelength, and total radiant exposure.<br><br>The subject device has been evaluated and found compliant with IEC 60601-1 (General Safety), IEC 60601-1-2 (Electromagnetic Compatibility), IEC 60601-2-57 (Particular requirements for non-laser light source equipment), and IEC 62471 (Photobiological Safety of Lamps and Lamp Systems).<br><br>Accordingly, the slight differences in treatment times do not raise new questions of safety or effectiveness. |
| **Software Controlled** | Device uses a timer and software to control treatment duration | Not publicly available (assumed - Device uses a timer and software to control treatment duration) | Device uses a timer and software to control treatment duration | Device uses a timer and software to control treatment duration. | Same | N/A |
| **Compliance with Voluntary Standards** | IEC 60601-1:2020<br>IEC 60601-1-2:2020<br>IEC 60601-1-11:2020<br>IEC 60601-2-83: 2019<br>IEC TS 60601-4-2<br>IEC 62471:2006<br>IEC 62133-2:2017 | IEC 60601-1:2020<br>IEC 60601-1-2:2020<br>IEC 60601-1-11:2020<br>IEC 60601-2-57:2011<br>IEC 62471:2006<br>IEC 62133-2:2017 | IEC 60601-1:2005<br>IEC 60601-1-2:2014<br>IEC 60601-1-11:2015<br>IEC 60601-2-57:2023<br>IEC 62471:2006<br>IEC 62133-2 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>IEC 62471<br>IEC 60601-2-57<br>IEC 62133-2 | Similar | The subject device declares conformity to IEC 60601-2-83:2019 (AMD1:2022) in lieu of IEC 60601-2-57. This is a more appropriate standard for a home-use device as IEC 60601-2:55 explicitly |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Tertiary Predicate Device | Verdict | Rationale |
|---|---|---|---|---|---|---|
| | | | | | | excludes home-use appliances from its scope. IEC 60601-2-83 imposes additional home-use safety requirements (IP rating, skin detection, lay-user labelling) that IEC 60601-2-57 does not address. Both predicates and the reference device cite IEC 60601-2-57, however, recent cleared home-use LED masks (K251042, K241857, K242796) have successfully cited IEC 60601-2-83. The use of IEC 60601-2-83 represents a safety standard for the subject device.<br><br>All other referenced standards are consistent with or equivalent to those cited by the predicate devices and reference device. |
| **Biocompatibility** | ISO-10993-1<br>ISO 10993-5<br>ISO 10993-10<br>ISO 10993-23 | ISO 10993-5<br>ISO 10993-10<br>ISO 10993-23 | ISO-10993-1<br>ISO 10993-5<br>ISO 10993-10<br>ISO 10993-23 | ISO-10993-1<br>ISO 10993-5<br>ISO 10993-10 | Same | N/A |

**Substantial Equivalence Conclusion:**

The CurrentBody Skin LED Multi Light Therapy Mask has the same intended use as the cited predicate devices and employs similar non-coherent LED technology to deliver visible and near-infrared light to intact facial skin for the treatment of wrinkles and mild to moderate inflammatory acne.

Any differences in wavelength configuration, LED distribution, or irradiance levels do not alter the fundamental technological characteristics and do not raise new questions of safety or effectiveness; therefore, the subject device is substantially equivalent to the predicate devices.

**Non-Clinical Testing (Performance/Bench Testing):**

The CurrentBody Skin LED Multi Light Therapy Mask (MK-110D) has been evaluated to establish the safety and performance of the device via laboratory bench testing as detailed in the below sections.

**Electrical Safety Testing:**

| Standard | Title | Version | Recognition Number | Test Result |
|---|---|---|---|---|
| IEC 60601-1 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | Edition 3.2 2020-08 | 19-49 | Pass |
| IEC 60601-1-11 | 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 | Edition 2.1 2020-07 | 19-38 | Pass |
| IEC 60601-1-2 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests | Edition 4.1 2020-09 | 19-36 | Pass |
| IEC TS 60601-4-2 | Medical electrical equipment - Part 4-2: Guidance and | IEC TS 60601-4-2: Edition 1.0 2024-03 | 19-50 | Pass |

| Standard | Title | Version | Recognition Number | Test Result |
|---|---|---|---|---|
| | interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems | | | |
| IEC 60601-2-83 | Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment | Edition 1.0 | N/A | Pass |
| IEC 62471 | Photobiological safety of lamps and lamp systems | First edition 2006-07 | 12-249 | Pass |
| IEC 62133-2 | 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 | Edition 1.0 2017-02 | 19-33 | Pass |

**Biocompatibility:**

The patient directly contacting materials in the CurrentBody Skin LED Multi Light Therapy Mask are showed in the following list:

| Components of Subject Device | Material of Components | Body Contact Category (ISO 10993-1) | Contact Duration (ISO 1993-1) |
|---|---|---|---|
| Inner Surface of face mask | Silicone | Surface-contacting device: skin | A – Limited (<24 hours) |
| Controller | ABS+PC | Surface-contacting device: skin | A – Limited (<24 hours) |
| Velcro | TPU | Surface-contacting device: skin | A – Limited (<24 hours) |
| Eye Insert | Silicone | Surface-contacting device: skin | A – Limited (<24 hours) |

The nature of body contact is surface medical device-intact skin contact and the contact duration is less than 24 hours. As per ISO 10993-1 Table 1 – Initial evaluation tests for consideration, the applicable biological effect is:

- Cytotoxicity
- Irritation or intracutaneous reactivity
- Sensitization

The component materials of the subject device, specifically the mask inner shell and outer shell are identical in formulation and processing to the corresponding component materials of the previously cleared device (K221444: LED Eye Perfector, Model: EY-36A). No additional chemicals have been introduced into these components, including but not limited to plasticizers, fillers, color additives, cleaning agents, or mold release agents.

The eye protection components of the subject device are identical in formulation, processing and geometry to the eye protection of the previously cleared device (K242593: CurrentBody LED 4 in 1 Zone Facial Mapping, Model: MK-90C). Similarly, no additional chemicals have been introduced into these components.

Furthermore, the inner surface of the CurrentBody Skin LED Multi Light Therapy Mask (silicone) is identical to cleared device (K242593) in formulation, processing, and cleaning. No other chemicals have been added (including but limited to plasticizers, fillers, color additives, clearing agents, mold release agents).

The material supplier, material grade and manufacturing specifications of the aforementioned components remains unchanged and identical to that in the referenced devices (K221444 & K242593).

Accordingly, the biocompatibility data on file for the referenced cleared devices (K221444 & K242593) is directly applicable to the subject device, and no new biocompatibility testing is necessary to demonstrate compliance with the applicable ISO 10993 endpoints.

These cleared devices serve as a reference for the established biocompatibility history of the materials, not as predicate devices for the current submission.

**Software Verification and Validation:**

Software verification and validation testing was conducted and documentation has been provided as per FDA's Guidance for Industry and FDA Staff document, "*Content of Premarket Submissions for Device Software Functions*".

In addition, as per, '*Content of Premarket Submissions for Device Software Functions'*, **Basic Documentation** has been determined as appropriate, due to the software supporting limited, well-defined device functions that does not perform diagnostic or clinical decision-making as well as incorporating predefined operating parameters and hardware-based safety controls. The device does not include wireless communication, external interfaces, data storage, or adaptive algorithms.

Furthermore, as per IEC 62304:2006/ AMD1:2015, the software system has been classified as **Software Safety Class B**, reflecting the potential for non-serious injury in the absence of mitigations.

**Cybersecurity:**

The subject device does not have any external or network interfaces and does not connect to other systems. As per FDA's Guidance for Industry and FDA Staff document, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*", the CurrentBody Skin LED Multi Light Therapy Mask is not reasonably susceptible to cybersecurity threats. As such, the CurrentBody Skin LED Multi Light Therapy Mask does not meet the definition of a 'cyber device' and

therefore, a cybersecurity risk assessment and related documentation is not applicable to this submission.

**Animal Studies:**

No animal studies were conducted as part of this submission in order to demonstrate substantial equivalence.

**Clinical Studies:**

Clinical performance testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

**Conclusion:**

The subject device (CurrentBody Skin LED Multi Light Therapy Mask) is as safe, as effective and performs as well as or better than the legally marketed predicate devices (K251588, K242593 and K260129).