November 27, 2024

SharkNinja Operating, LLC
% Lynette Zentgraft
Senior Advisor
Covington & Burling, LLP
One CityCenter
850 Tenth Street, NW
Washington, District of Columbia 20001

Re: K242796
Trade/Device Name: CryoGlow (FW3XXXX)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHS, OLP
Dated: September 16, 2024
Received: September 16, 2024

Dear Lynette Zentgraft:

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: 2024.11.27 09:58:09 -05'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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)*
K242796

Device Name
CryoGlow (FW3XXXX)

Indications for Use *(Describe)*
The CryoGlow LED mask emits energy in the red and infrared light spectrum for the treatment of fine lines and wrinkles and in the red, blue, and infrared light spectrum for the treatment of mild-to-moderate inflammatory acne.

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 K242796

Date:	November 13, 2024
Submitter:	SharkNinja Operating, LLC 89 A Street, Suite 100 Needham, MA 02494
Contact person:	Alyssa Aquino Email: AAquino@sharkninja.com Tel: 617-546-5768
Application Correspondent:	Lynette Zentgraft Covington & Burling, LLP Email: lzentgraft@cov.com Tel: 202-662-5404
Device Trade Name:	CryoGlow LED mask (FW3XXXX)
Common Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name:	Light Based Over the Counter Wrinkle Reduction Device
Classification:	Class II
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4810
Product Code:	OHS, OLP
Predicate Device:	TheraFace K230293 Product codes OHS, OLP 21 CFR 878.4810 Class II
Reference Device:	MZ Skin LightMAX Supercharged LED Mask 2.0 K213184

Product codes OHS, OLP
23 CFR 878.4810
Class II

Indications for Use

The CryoGlow LED mask emits energy in the red and infrared light spectrum for the treatment of fine lines and wrinkles and in the red, blue and infrared light spectrum for the treatment of mild-to-moderate inflammatory acne.

Device Description

The CryoGlow mask is an over-the-counter (OTC) beauty device intended to emit energy in the red and infrared spectrum to treat fine lines and wrinkles, and in the red, blue, and infrared light spectrum to treat mild-to-moderate inflammatory acne. It is made of molded plastic and is designed to be worn over the face. The device incorporates 480 LEDs (160 tri-wick packages) that emit combinations of red, blue, and infrared light depending on the skin routine chosen. The mask also incorporates under-eye cooling technology. Using the attached remote controller and graphical user interface, users may choose from three skin care routines: Better Aging (red and infrared light), Skin Clearing (blue, red and infrared light), and Skin Sustain (blue and red light). During each routine, a combination of red, blue, and infrared light is emitted for a prescribed amount of time.

The CryoGlow mask also incorporates an under-eye cooling function. Peltiers and fans are used to cool the built-in chill pads (cool sinks) that rest on the surface of the skin under the eyes. The cooling feature turns on automatically with each skin routine, but users may turn off the under-eye cooling function during a skin care routine or run a stand-alone under-eye cooling session. The cooling function is intended to refresh/invigorate/soothe the skin. Optional clip-on chill pads are provided with the device to help achieve the proper fit.

Silicone eye shields are built into the design of the mask to help protect the user's eyes from the LED light during a treatment routine. Other built-in safety features include an automatic shut off and auto-dimming feature where the LED lights dim when the mask is away from the user's face. Electrical, mechanical, optical, and thermal safety testing has been conducted to support the safety and effectiveness of the mask.

The CryoGlow mask must be charged prior to use and is provided with a USB-A to USB-C charging cord and USB-A charging block. An optional charging stand is provided separately.

Substantial Equivalence

Substantial equivalence is based on comparison to the predicate TheraFace device and reference MZ Skin LightMAX reference device.

Elements of Comparison	**Proposed Device CryoGlow**	**Predicate Device TheraFace**	**Reference Device MZ Skin LightMAX Supercharged LED Mask 2.0**	**Comment**
510(k)Submission Number		K230293	K213184	
Trade Name	CryoGlow	TheraFace	MZ Skin LightMAX Supercharged LED Mask 2.0	
Product Code	OLP, OHS	OLP, OHS	OLP, OHS	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Class	Class 2	Class 2	Class 2	Same
Indication for Use	The CryoGlow LED mask emits energy in the red and infrared light spectrum for the treatment of fine lines and wrinkles and in the red, blue and infrared light spectrum for the treatment of mild-to-moderate inflammatory acne.	Red light is intended to treat full face wrinkles Blue light is intended to treat mild to moderate inflammatory acne Red and infrared light is intended to treat full face wrinkles	The MZ Skin LightMAX Supercharged LED Mask 2.0 is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. The MZ Skin LightMAX Supercharged LED Mask 2.0 is an over-the-counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles.	Similar to the predicate device and reference device.
Prescription/OTC	OTC	OTC	OTC	Same
Power Source	2 Li-Ion Batteries 3.6V, 2350 mAh total, charged by USB-A to	5-15V DC 2.5A max powered by 2 Li-Ion Batteries	Rechargeable Li-Ion polymer battery	Similar

	USB-C charging cord to USB-A charging block	3.7V 1500mAh), charged via Universal USB charger cord or fast charger adaptor		
Software/Firmware/Microprocessor Control	Yes	Yes	Yes	Same
Power (mW/cm^2)	**Skin Sustain:** Blue 59.8 ± 7 mW/cm², Red 17.0 ± 5mW/cm², IR 51.2 ± 5 mW/cm² Total mode = 128 mW/cm² **Skin Clearing [Step 1]:** Blue 64 ± 8 mW/cm², IR 64.0 ± 5 mW/cm² Total mode =128 mW/cm² **Skin Clearing [Step 2]:** Blue 55 ± 6 mW/cm², Red 73 mW/cm² Total mode =128 mW/cm² **Skin Clearing [Step 3]:** Red 73 mW/cm², IR 55 ± 5mW/cm², Total mode =128 mW/cm² **Better Aging:** Red 64 ± 5mW/cm², IR 64 ± 5 mW/cm² Total mode = 128 mW/cm²	**Modes:** Red: 73 ± 5mW/cm² Blue: 64 ± 5mW/cm² Red+IR: 73 ± 5mW/cm² / 55 ± 5 mW/cm² = 128mW/cm²	**Acne:** Blue 28mW/cm² Red 16 mW/cm² Total = 44 mW/cm^2 **Wrinkles:** Red 19 mW/cm² NIR 11 mW/cm² Total = 29 mW/cm²	Similar to the predicate device

Total Dose for all LEDs	**Skin Sustain:** Total Blue dose = **137.4** J/cm² Total Red/IR = **156.7** J/cm² **Skin Clearing [Step 1]** Total Blue dose = **27.1** J/cm² Total Red/IR = **27.1** J/cm² **Skin Clearing [Step 2]** Total Blue dose = **110.2** J/cm² Total Red/IR = **146.2** J/cm² **Skin Clearing [Step 3]** Total Red/IR = **258.1** J/cm² **Skin Clearing Total** Total Blue dose = **137.4** J/cm² Total Red/IR = **431.4** J/cm² **Better Aging** Total Red/IR = **431.4** J/cm²	Blue = **137.4** J/cm² Red = **156.7** J/cm² Red+IR = **274.7** J/cm² Total/cumulative dose (modes are run back-to-back): Blue = **137.4** J/cm² Red & IR = **431.4** J/cm² Total = **568.8** J/cm²	**Acne:** Blue 16.8 J/cm^2 Red 9.6 J/cm2 **Wrinkles:** Red 11 J/cm^2 NIR 7 J/cm^2	Similar to the predicate device.
Wavelength	Red: 630 ±10nm Blue: 415 ±10nm IR: 830 ± 10 nm	Red: 633 ±10nm Blue: 415 ±10nm Red+IR:633nm ±10nm/830 ± 10 nm	Red: 630 ±10nm Blue: 415 ±10nm NIR: 833 ±10nm	Same
Irradiance Source	LEDs	LEDs	LED	Same
Total Number of LEDS	480 (160 tri-wick packages)	648 (216 tri-wick packages)	unknown	Similar to the predicate device (the size of the of LEDs are the same)

Treatment Duration	Skin Sustain: 4.3 min (daily after 8 weeks) Skin Clearing: 8.4 min (daily for at least 8 weeks) Better Aging: 6.4 min (daily for at least 8 weeks) Under-eye cooling: may be used with LED treatments or can be used without LEDs active. Variable cooling settings are available and may be adjusted by the user. Cooling is intended for refreshing/invigorating/ soothing the skin only.	LED: 3 minutes each light mode for a total of 9 minutes per treatment, recommended to use 2 to 5 times per week. Vibration: accompanies LED treatments or can be used without LED's active. 3 vibration patterns, 5 minutes each, for a total of 15 minutes. During blue light treatment mode, vibration is not active around the eyes. Vibration is included for a more relaxing experience.	10 mins (may be stopped at any time) Acne: 4 x weeks, 6 weeks Wrinkles: 5 x weeks, 6 weeks	Similar to both the predicate and reference devices.
Main Materials	ABS + MABS	PC + ABS	Methyl vinyl silicone rubber	Similar
Tested for Electrical Safety?	Yes Tested against IEC 60601-1 (see cover note to electrical, mechanical, and thermal testing section)	Yes Complies with IEC 60601-1	Yes Complies with IEC 60601-1	Same
Tested for Photobiological Safety?	Yes Complies with IEC 62471 Complies with IEC 60601-2-83	Yes Complies with IEC 62471 Complies with IEC 60601-2-57	Yes Complies with IEC 62471	Same
Tested for EMC?	Yes Complies with IEC 60601-1-2	Yes Complies with IEC 60601-1-2	Yes Complies with IEC 60601-1-2	Same

Tested for Biocompatibility?	Yes Complies with: ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	Yes Complies with: ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-23	Yes Complies with: ISO 10993-1 ISO 10993-5 ISO 10993-10	Same

The CryoGlow, TheraFace predicate device and MZ Skin LightMAX reference device, use light emitted from LEDs in the blue, red, and infrared spectrum to treat facial wrinkles and mild-to-moderate inflammatory acne. Both the CryoGlow and predicate device use red and infrared light to treat facial wrinkles. CryoGlow emits light in the blue, red, and infrared spectrum to treat mild-to-moderate acne, which is equivalent to the reference MZ Skin LightMAX reference device (for purposes of the CryoGlow device, red and infrared light are considered equal).

Both the CryoGlow and predicate device are powered by 2 Li-Ion battery cells and provided with a charging cord and USB charging block. Differences between the batteries, charging cord, and charging block are minor and will not affect safety or effectiveness.

Although the predicate device includes more LEDs, the size of the individual LEDs is the same as those used in the predicate device. Testing demonstrates that the LED distance from the face is such that the CryoGlow LED beams overlap by the time they reach the skin, uniformly distributing light. Additionally, the calculated median distance between the LEDs included in the CryoGlow is essentially equivalent to the calculated median distance between the LEDs included in the predicate device. These results show that, despite the differences in the number of LEDs, the distribution of light over the treatment area from the CryoGlow mask is substantially equivalent to the distribution of light from the TheraFace mask.

The treatment times and routines offered by the CryoGlow device differ from those of the predicate TheraFace device. For purposes of demonstrating substantial equivalence, the total energy delivered from the device into the face is the critical parameter, which takes into consideration multiple parameters of the LEDs, including wavelength, power/power density, treatment time, treatment area, and the number of LEDs. Research and technical analyses demonstrate that the power density for the predicate TheraFace device and CryoGlow are equivalent. Additional research supports that, when calculating the overall dose for CryoGlow, red and infrared light are considered equal. Using the treatment times for each mode, the calculated overall dose provided by CryoGlow is equivalent to the total/cumulative dose provided by the predicate TheraFace device when used to treat both facial wrinkles and mild-to-moderate inflammatory acne. Additionally, the power mode densities of the individual red, infrared, and blue LEDs of CryoGlow do not exceed those of the TheraFace device.

The CryoGlow treatment times are slightly different than those of the predicate; however, as described above, the total dose provided by the device in each mode (Skin Sustain, Better Aging, and Skin Clearing) is the same as that provided by the predicate device.

Although there are differences between the number of LEDs, power/power density, modes, and treatment times between the CryoGlow and predicate device, the total energy delivered to the

face from the CryoGlow device is substantially equivalent to that delivered by the predicate TheraFace device. Therefore, these differences do not raise new questions of safety or effectiveness as compared to the predicate device.

There are minor differences in the materials of the CryoGlow device as compared to the predicate TheraFace device. However, both devices are made of molded plastic, so this difference does not raise new questions of safety or effectiveness.

The predicate TheraFace device includes vibration, whereas the CryoGlow does not. The CryoGlow includes under-eye cooling technology, which the predicate does not. The vibration function of the predicate does not impact the safety or effectiveness of the device for the treatment of wrinkles and acne; rather, it is intended for relaxation purposes. Similarly, the under eye cooling feature of CryoGlow is for purposes of refreshing/invigorating/soothing the skin only and does not impact the device's safety or effectiveness in treating fine lines, wrinkles or acne. Therefore, this difference does not raise new questions of safety or effectiveness.

Non-Clinical Testing

To establish substantial equivalence to the predicate device, the CryoGlow was tested against the applicable standards for electrical safety, EMC, and biocompatibility, as listed in the Substantial Equivalence Comparison Table above.

Product Safety and EMC performance was tested against the following industry standards:

- IEC 60601-1:2005/AMD2:2020
- IEC 60601-1-2:2014 +AMD1:2020
- IEC 60601-1-11:2015/AMD1:2020
- IEC 62471:2006

Bench testing was conducted to verify the peak wavelength of each light spectrum and to demonstrate that the power/power density of the CryoGlow LEDs is equivalent to that of the predicate device. Using the power/power density values, the total energy (amount of light delivered to the skin) for each CryoGlow mode (Skin Sustain, Better Aging, and Skin Clearing) was calculated and determined to be substantially equivalent to the total energy by the TheraFace device. The median distance between the LEDs in the CryoGlow device was also calculated, and was determined to be essentially equivalent to that of the TheraFace device. This, along with additional bench testing, confirmed that the distribution of light from the CryoGlow mask is uniform and is substantially equivalent to that of the predicate TheraFace device, despite the difference in the number of LEDs.

Additionally, Design Verification and Validation Testing was conducted to confirm that CryoGlow meets the design requirements and performs as intended. A human factors/usability study was conducted to demonstrate that CryoGlow can be used safely and effectively by its intended users, for the intended use of the device, and in the intended use environment. FDA's guidance document "Applying Human Factors and Usability Engineering to Medical Devices" (February 3, 2016) was considered when conducting this testing.

Conclusion

Both the CryoGlow and predicate device have the same intended use. The technological differences between the CryoGlow mask and the predicate device do not raise new questions of safety or effectiveness. Therefore, the CryoGlow is substantially equivalent to the predicate TheraFace device.