January 18, 2024

InWound ApS
Otto Ømann,Coo
Søndervigvej 50
Copenhagen, 2720
Denmark

Re: K233077
Trade/Device Name: FlashHeal 2 (FlashHeal 2.0)
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: GEX, ILY
Dated: December 22, 2023
Received: December 22, 2023

Dear Otto Ømann:

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.

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
Tanisha L. Hithe -S 2024.01.18 14:42:47 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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.

Submission Number *(if known)*

K233077

Device Name

FlashHeal 2 (FlashHeal 2.0)

Indications for Use *(Describe)*

FlashHeal's use of blue, red, and infrared regions of the light spectrum is intended to emit energy to treat and document dermatological conditions.
i. The blue light (405 nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
ii. The red light (625 nm wavelength) is generally indicated to treat superficial, benign vascular, and pigmented lesions.
iii. The infrared light (850 nm wavelength) is generally used 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 where applied.
iv. The red and infrared lights combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.
FlashHeal does not diagnose the patient and does not come in contact with the patient at any point.

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) #: K233077

510(k) Summary

Prepared on: 2024-01-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	InWound ApS
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Correspondent Contact Telephone	+45 53 77 74 54
Correspondent Contact	Mr. Otto Ømann
Correspondent Contact Email	otto@inwound.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FlashHeal 2 (FlashHeal 2.0)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190938	Phototherapy Systems	GEX
K200659	Dermalux Tri-Wave MD	GEX
K221083	Smartlux Mini	GEX
K222751	LED Light Therapy Device, KN-7000L	GEX

Device Description Summary

21 CFR 807.92(a)(4)

FlashHeal 2 (FlashHeal 2.0 model) is an Rx Only mobile medical device that delivers LED therapies for managing dermatological conditions using various narrow-band wavelengths of blue (405 nm), red (625 nm), and infrared (850 nm) light without any direct patient contact.

The LEDs light source is placed inside an End-effector mounted on a mechanical arm maneuvered by the healthcare professional. The system is operated by a touchscreen interface which allows the user to configure the treatment settings.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

FlashHeal's use of blue, red, and infrared regions of the light spectrum is intended to emit energy to treat and document dermatological conditions.
i. The blue light (405 nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
ii. The red light (625 nm wavelength) is generally indicated to treat superficial, benign vascular, and pigmented lesions.
iii. The infrared light (850 nm wavelength) is generally used 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 where applied.
iv. The red and infrared lights combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.
FlashHeal does not diagnose the patient and does not come in contact with the patient at any point.

Indications for Use Comparison

21 CFR 807.92(a)(5)

FlashHeal 2.0 device has the same indications for use as the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

FlashHeal 2.0, despite exhibiting minor deviations in blue irradiance and treatment area, maintains similar technological characteristics to its predecessors. Any variance in maximum dosage is minimal, affirming the device's safety. This does not alter the device's Risk Group level (2), ensuring compliance with established safety standards. The device also includes safety enhancements like skin temperature monitoring. InWound supplies safety goggles with the necessary Optical Densities (ODs) for eye protection. Bench validation testing has verified that the differences between the devices do not affect effectiveness in the targeted treatment area. It's important to note that FlashHeal 2.0 is not intended for treating large areas, which aligns with its safety and effectiveness profile.

Therefore, based on its design and manufacturing, FlashHeal 2.0 has been demonstrated to be very similar to the referenced predicate devices in terms of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Performance testing of FlashHeal was conducted to verify that the device met all design specifications. The test results demonstrate that FlashHeal complies with all requirements, including international and FDA-recognized consensus standards:
-EN/IEC 60601-1 Ed. 3.2 en:2020-08 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
-EN/IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
-IEC/TR 60601-4-2 Ed. 1.0 en:2016 Medical Electrical Equipment - Part 4-2: Guidance And Interpretation - Electromagnetic Immunity: Performance Of Medical Electrical Equipment And Medical Electrical Systems
-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
Additionally, software documentation and related procedures were submitted to an external reviewer, which declared compliance according to the IEC 62304:2006 +AMD1:2015 standard. Performance testing in relation to the above-mentioned standards has been carried out by a 3rd party testing lab.

Bench validation testing was performed with an irradiance sensor to gather relevant statistical information regarding FlashHeal 2.0's optical output and graphical information about the light distribution in the treatment area. The results indicate that the device maintains the desired irradiance across the entire operational distance range, with deviations remaining below ±20%. Additionally, the effective irradiance does not exceed 186 mW/cm^2. The irradiance maps, standard deviations, and overall deviations show a good uniformity of the optical output and within the project and software requirements. Therefore, FlashHeal 2.0 is as effective as the predicate devices as it can deliver the promised irradiance and in accordance with the reference device.

Clinical testing is not applicable.