March 29, 2024

CyDen Limited
Adam Stephens
Regulatory Engineer
Block A, Bay Studios Business Park
Fabian Way, SA1 8QB
Swansea,
United Kingdom

Re: K240587
Trade/Device Name: SmoothSkin Pure Unplugged (SSB3)
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: OHT, GEX
Dated: February 29, 2024
Received: March 1, 2024

Dear Adam Stephens:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2024.03.29 11:45:19 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

SmoothSkin Pure Unplugged (SSB3)

Indications for Use *(Describe)*

The SmoothSkin Pure Unplugged is intended for the removal of unwanted hair. The SmoothSkin Pure Unplugged is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Prepared on: 2024-03-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	CyDen Limited
Applicant Address	Block A, Bay Studios Business Park Fabian Way, SA1 8QB Swansea United Kingdom
Applicant Contact Telephone	+44 1792 274009
Applicant Contact	Mr. Adam Stephens
Applicant Contact Email	astephens@cyden.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SmoothSkin Pure Unplugged (SSB3)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Light Based Over-The-Counter Hair Removal
Regulation Number	878.4810
Product Code(s)	OHT, N/A

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213692	SmoothSkin Pure Mini	OHT
K143003	SmoothSkin Gold	OHT

Device Description Summary

21 CFR 807.92(a)(4)

The SmoothSkin Pure Unplugged is an over the counter IPL (Intense Pulsed Light) Hair Removal device for home use.

The device is battery powered and charged by mains. The device consists of the handset with removal battery pack, Handset Dock station, and AC Adapter. AC mains is fed to the AC Adapter and converted to DC to charge the battery pack via the docking station contact pins, the device cannot be used when charging. The battery pack is used to charge the electrical storage capacitor, the stored energy is used to produce an optical output from the flash lamp.

Light energy is transferred through the skin's surface and is absorbed by melanin present in the hair shaft. The absorbed light energy is converted to heat energy (below the surface of the skin), which reduces the hairs growing back.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SmoothSkin Pure Unplugged is intended for the removal of unwanted hair. The SmoothSkin Pure Unplugged is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The SmoothSkin Pure Unplugged has the same following technical characteristics:

- The same indicated use,
- Operates with the same mode of action,
- Has similar technological characteristics,
- Has the same materials,
- Has the same shelf life
- Is manufactured and packed in the same manner,
- Has similar output parameters to the predicate device,
- Has the same safety features.

The following changes have been made to the device:
- Energy Source Change; The device uses a removable battery pack that contains lithium-ion batteries for the devices energy source. The battery pack is charged via the dock station contact connectors which has an AC adapter connected to mains supply, the device cannot be used when charging.
- Electrical Architecture; modifications to the electrical architecture to allow the energy source change.
- Software; Modifications to the software for battery management.
- Aesthetic Appearance; minor modifications to the appearance of the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The device is compliant with the following Electrical Safety and Electromagnetic Compatibility standards.

1) AAMI / IEC 60601-1 : Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
2) IEC 60601-1-6 : Medical Electrical Equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
3) IEC 60601-2-57 : 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, cosmetic and aesthetic use
4) IEC 60601-2-83 : Medical Electrical Equipment: Part 2-83: Particular requirement for the basic safety and essential performance of home light therapy equipment
5) IEC 60601-1-2 : Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
6) IEC 62471 : Photobiological safety of lamps and lamp systems
7) IEC 62304 : Medical Device Software - Software Life Cycle Processes
8) 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
9) UL 2054 : Household and Commercial Batteries

The device is compliant with the following Biocompatibility standards

1) ISO 10993-1 : Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
2) ISO 10993-5 : Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
3) ISO 10993-10 : Biological evaluation of medical devices Part 10: Tests for skin sensitization