



Food and Drug Administration
10903 New Hampshire Avenue
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April 14, 2016

Cyden Limited
Dr. Mike Kiernan
Chief Scientific Officer
Technium 2, Kings Road
Swansea, SA1 8PJ GB Wales

Re: K160968

Trade/Device Name: Ipulse Smoothskin Gold Hair Removal Device
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: April 4, 2016
Received: April 6, 2016

Dear Dr. Mike Kiernan:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Jennifer R.
Stevenson -A**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not Known

K160968

Device Name: iPulse SmoothSkin Gold Hair Removal System

Indications for Use:

The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse Smoothskin Gold 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.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3.0 510(K) SUMMARY

Submission Date: 4th April 2016

Submitter Information

Company Name: CyDen Limited.

Company Address: Technium 2, Kings Road, Swansea, Wales, UK SA1 8PJ

Contact Person: Dr Mike Kiernan
UK +44 1792 485 519
mkiernan@cyden.com

Device Information

Trade Name: iPulse SmoothSkin Gold Hair Removal System

Common Name: Light based over the counter hair removal system

Classification Name: Laser surgical instrument for use in general and plastic surgery and dermatology

Device Class: 21 CFR 878.4810

Predicate Device: iPulse SmoothSkin Gold Hair Removal System
K143003
CyDen Limited

A comparison of the key technological characteristics of the iPulse SmoothSkin Gold System to the predicate device is provided in the following table.

	PREDICATE DEVICE	DEVICE
Device Name	iPulse SmoothSkin Gold	iPulse SmoothSkin Gold
K Number	K143003	
Manufacturer	CyDen Ltd	CyDen Ltd
Energy Medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Wavelength Range	510-1100nm	510-1100nm
Pulse Duration	2ms to 10ms	2ms to 10ms
Energy Density	3-6J/cm ²	3-6J/cm ²
Spot Size	3cm ² (3cm by 1cm)	3cm ² (3cm by 1cm)
Delivery Device	Direct Illumination to Tissue	Direct Illumination to Tissue
Pulsing Control	Finger switch	Finger switch
Skin Tone Sensor	Optical Measurement Integral to device. Continuous measurement.	Optical Measurement Integral to device. Continuous measurement.
Specific Indications for Use	The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse SmoothSkin Gold 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.	The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse SmoothSkin Gold 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.

Device Description:

The iPulse SmoothSkin Gold Hair Removal System is an intense pulsed light (IPL) system consisting of:

Handset – contained within the handset is the Capacitor, Capacitor Charger, Control electronics, Optics (Lamp, Filter, Reflector, Light Pipe), Trigger mechanism and Skin Tone / proximity Sensors (STS);
External Power Supply – used to convert the electricity from the mains supply (either 110V or 230V, 50/60Hz) to a lower DC value, typically 24V. This power supply unit is an “off-the-shelf” component which meets all the relevant electrical safety standards.

Intended Use

The iPulse SmoothSkin Gold Hair Removal System is an over the counter device intended for the removal of unwanted hair.

Indications for Use

The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse SmoothSkin Gold 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.

Performance Data – Non Clinical

Nonclinical and clinical testing has been completed on the iPulse SmoothSkin Hair Removal System. Nonclinical testing included biocompatibility electrical safety testing was performed to, and passed, the following standards:

- Electrical Safety - IEC 60601-1:2005+AMD1:2012 (3rd Edition)
- Electromagnetic Compatibility - IEC 60601-1-2:2014
- Photobiological safety of lamps and lamp systems - IEC 62471:2006
- Biocompatibility
 - ISO 10993-05, “Biological Evaluation of Medical Devices – Part 5:2009: Tests for In Vitro Cytotoxicity”
 - ISO 10993-12, “Biological Evaluation of Medical Devices – Part 12:2012(E): Sample Preparation and Reference Materials”
 - ISO 10993: Part 10:2010(E), “Tests for irritation and skin sensitization”

In addition, the software was validated to meet the principle of the FDA guidance document ‘General Principles of Software Validation’ and the necessary documentation provided.

Performance Testing – Clinical

A clinical trial was performed to assess the safety profile of the SmoothSkin Gold Hair Removal System when used on facial regions below the cheekline. A total of 31 subjects were enrolled, each treated 12 times on a weekly basis. Adverse events were recorded throughout the treatment period and at 1 week post and 3 months post last treatment. A total of 330 treatments were performed and a total of 5 “Device Related Events” (DRE) were recorded – equating to an adverse incident rate of 1.52%. All adverse events were minor in nature and resolved completely within 1-2 weeks. The adverse events reported were as listed in the table below.

Subject ID.	DRE Occurrence	DRE Description	Resolution
10	Post 8 th Treatment	Spots appearing at treatment site (pre-auricular)	Completely resolved within 1 week.
11	Post 5 th Treatment	Erythema at treatment site (pre-auricular)	Resolved within 2-3 days
14	Post 3 rd Treatment	Pruritus at treatment site (upper-lip)	Resolved within 1 week
25	Post 10 th Treatment	Spot at treatment site (pre-auricular)	Resolved within 2 weeks
31	Post 1 st Treatment	Delayed erythema appearing at treatment site (pre-auricular) several days after treatment	Resolved within 2-3 days.

Substantial Equivalence:

The iPulse SmoothSkin Gold Hair Removal System has the same intended use, mode of action and similar operational characteristics as the predicate device. Performance data supports that the device is as safe and effective as the predicate devices for its intended use. Therefore, the iPulse SmoothSkin Gold Hair Removal System may be found substantially equivalent to its predicate devices.