DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 18, 2015

iPulse Limited
Dr. Michael Kiernan
Chief Scientific Officer
Technium 2, Kings Road, The Docks
Swansea, Wales SA1 8PJ, Wales, United Kingdom

Re: K143003
Trade Name: iPulse SmoothSkin Gold Hair Removal System
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, ONX, GEX
Dated: May 15, 2015
Received: May 18, 2015

Dear Dr. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143003

Device Name
iPulse SmoothSkin Gold Hair Removal System

Indications for Use *(Describe)*
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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 3.0 510(K) SUMMARY

Submission Date: 15th October 2014

Submitter Information

Company Name: iPulse 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 Devices: iPulse Smoothskin Hair Removal System
K130315
CyDen Limited

The Shaser HRS2 IPL Hair Removal System
K120080
ShaserInc

mē
K131649
Syneron Beauty Ltd

A comparison of the key technological characteristics of the iPulse Smoothskin Gold System to the predicate devices is provided in Table 1.

| | PREDICATE DEVICES | | | DEVICE |
|---|---|---|---|---|
| **Device Name** | **iPulse Hair Removal System** | **Shaser HRS2 IPL** | **mē** | **iPulse Smooth Skin Gold** |
| **K Number** | K130315 | K120080 | K131649 | K143003 |
| **Manufacturer** | CyDen Ltd | ShaserInc | Syneron Beauty Ltd | iPulse Ltd |
| **Energy Medium** | Xenon Arc Flashlamp | Xenon Arc Flashlamp | Xenon Arc Flashlamp | Xenon Arc Flashlamp |
| **Wavelength Range** | 530-1100nm | 650-1100nm* | 550-1200nm | 510-1100nm |
| **Pulse Duration** | Variable -<br>Single pulse 25milliseconds.<br>to<br>Double Pulse 20ms on, 60 ms off. | 30 milliseconds | ~5ms | 2ms to 10ms |
| **Energy Density** | 7-10J/$cm^2$ | 9J/$cm^2$ | Up to 9J/cm2 | 3-6J/$cm^2$ |
| **Spot Size** | 3$cm^2$ (1.3cm by 2.4 cm) | 2$cm^2$ (1cm by 2cm) | 3.3cm2 (3.3cm by 1.0cm) | 3$cm^2$ |
| **Delivery Device** | Direct Illumination To Tissue | Direct Illumination to Tissue | Direct Illumination to Tissue | Direct Illumination to Tissue |
| **Pulsing Control** | Finger switch | Finger switch | Finger Switch | Finger switch |
| **Skin Tone Sensor** | Optical Measurement Removable from Base Unit.<br><br>Sensor moveable to treatment site | Optical Measurement Integral to Base Unit<br><br>Sensor fixed in base unit, treatment site moved to sensor | Electrical Contact | Optical Measurement Integral to device.<br><br>Continuous measurement. |
| **Specific Indications for Use** | The iPulse Hair Removal System is an Over-the-counter device intended for the removal of unwanted hair. | The Shaser HRS2 is an Over-the-counter device intended for the removal of unwanted hair. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the numbers of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regimen. | The me is an over-the-counter device indicated for the removal of unwanted hair. Me is also intended for permanent in hair growth following an initial treatment regimen with or without maintenance when measured at 6,9 and 12 months. | 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. |

**Table 1: Predicate Device Comparison**

**Device Description**

The iPulse SmoothSkin 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, clinical and usability testing has been completed on the iPulse SmoothSkin Hair Removal System. Nonclinical testing included biocompatibility, electrical safety and software testing.

Usability testing was completed in 24 subjects to evaluate device human factors and label comprehension.

**Performance Data – Clinical**

Clinical testing was conducted in 50 subjects at a single treatment center. Each subject received 12 weekly treatments to the selected body location. Prior to treatment the site was shaved and any hair trimmings removed. The treatment was performed by a suitable operator to ensure consistency of coverage thus enabling accurate efficacy determination. The device output setting for each subject was determined by the measured skin tone at the actual treatment site.

Hair counts were performed on a fixed area located at the center of the treatment site using templates and skin landmarks. All treatment sites were photographed prior to each treatment and at the review point. All subjects were shaved one week prior to both baseline and the 6 and 12 month review points thus ensuring hair count consistency.

Hair counts in the selected area on each subject were determined by 2 independent assessors and the results averaged. The percentage difference in hair count pre and post treatment was calculated and a Paired Sample t-test used to compare means. Only cases where the pre and post treatment hair count areas could be clearly identified on the clinical photographs were analysed.

The efficacy results are provided in Table 2.

| | **SmoothSkin Gold** |
|---|---|
| Number of Subjects at 6 Months Post Treatment | 50 |
| Hair Reduction at 6 Months Post Treatment | 43.9% |
| | |
| Number of Subjects at 12 Months Post Treatment | 33 |
| Hair Reduction at 12 Months Post Treatment | 36.0% |
| | |
| % of Subjects met success (>30% hair reduction) on all body areas at 12 months post-treatment. Subject Success is defined as greater than 30% hair reduction at all treatment sites at 12 months.* | 66.7% |
| ** The SmoothSkin Gold clinical study only used single treatment sites on individual subjects.* | |

**Table 2: Clinical Efficacy Results**

**Substantial Equivalence**

The iPulse SmoothSkin Gold Hair Removal System has the same intended use, mode of action and similar operational characteristics as the predicate devices. Any minor differences between the iPulse Smoothskin Gold Hair Removal System and the listed predicate devices do not raise any issues of safety or efficacy. Performance data supports that the device is as safe and as 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.