January 18, 2018

Conair Corporation
% Mr. E.J. Smith
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K172791
Trade/Device Name: Lumilisse IPL Hair Remover
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
Dated: October 20, 2017
Received: October 20, 2017

Dear Mr. Smith:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172791

Device Name
Lumilisse Hair Removal System

Indications for Use *(Describe)*
The Lumilisse IPL (Intense Pulsed Light) Hair Remover is an over-the-counter device intended for the removal of unwanted hair.

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

Sponsor: Conair Corporation

Address: One Cummings Point Road

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Telephone Number: 203-975-4617

Contact Person: Mike Cantrell

Regulatory Compliance

Email: mike_cantrell@conair.com

Summary Preparation Date: January 18, 2018

Device Name:

Classification Name: Light based OTC Hair Remover

Common/Usual Name: Light based OTC Hair Remover

Proprietary Name: Lumilisse IPL Hair Remover

Establishment Registration: 1222304

Classification: Class II

Product Code: OHT

Code of Federal regulation: 21 CFR 878.4810

Review Panel: General Surgery Devices Branch One - Light Based/Laser

Predicate Device:

Predicate	Manufacturer	Brand Name	510(k) Number
Primary	Home Skinovations Ltd.	Silk'n Flash N Go	K103184
Reference	Syneron Beauty Ltd.	mē	K131649
Reference	CyDen Ltd.	iPulse Smoothskin Gold	K160968

Device Description:

The Lumilisse IPL Hair Remover (Figure 11.1) is a hair-removal device that eliminates unwanted hair from the body (legs and arms), and from more sensitive areas (underarms, bikini line, lower half of the face - below the cheekbones) using intense pulse light technology.

The Lumilisse IPL Hair Remover is an Intense Pulsed Light (IPL) system consisting of:

- Handset – contained within the handset is the High Voltage Capacitor, Capacitor Charger, Control Electronics and Firmware, Quartz Light Tube, Cooling System, Skin Tone and Skin Contact Sensors and the firmware for operation and safety.
- External Power Supply – used to convert the electricity from the mains supply (either 110V or 230V, 50/60Hz) to a much lower DC value. This power supply unit is an "off-the-shelf" component which meets all the relevant electrical safety standards.
- Skin Color Sensor System – For effective and safe treatment, the Lumilisse IPL Hair Remover is equipped with the Skin Sensor System, a skin color detection system that automatically regulates the light intensity applied to the skin.
- Levels of Intensity - The Lumilisse IPL Hair Remover features 5 levels of intensity, running from the lowest (level 1) to the highest (level 5). The level of intensity indicates the intensity of the pulsed light applied to the skin when using the Lumilisse Hair Remover.

The Lumilisse Hair Remover can be used by men and women aged 21 and older.

Device Indications for Use:

The Lumilisse IPL (Intense Pulsed Light) Hair Remover is an over-the-counter device intended for the removal of unwanted hair.

Discussion of Technological Characteristics:

Discussion of Similarities

The Lumilisse IPL Hair Remover and the predicate devices have the same IPL technology, capacitance-based skin contact sensor such that if the flash port is not in direct contact with the skin (covering the entire port) the unit will not flash, skin tone sensors, pulse durations, indications for use, use environment, user group, power source, operating/storage temperature and relative humidity conditions. The Lumilisse IPL Hair Remover has the identical wavelengths as the mē.

Discussion of Differences K103184:

The Lumilisse IPL Hair Remover lowest light intensity reading is 2.0 J/cm^2 versus predicate's lowest light intensity of 3.0 - 5.0 J/cm^2 and the Lumilisse IPL Hair Remover wavelength range is 550 nm – 1200 nm versus the predicate device wavelength range of 475 nm – 1200 nm. The differences in light intensity and wavelength raise no new issues of safety and effectiveness.

Discussion of Differences K131649:

The Lumilisse IPL Hair Remover maximum light intensity is 4.5 J/cm^2 versus the predicate's maximum light intensity of 4 J/cm^2 and the difference raises no new issues of safety and effectiveness.

Discussion K160968:

The Lumilisse IPL Hair Remover has a wavelength of 550-1200nm and the predicate has a wavelength of 510-1100nm. The Lumilisse IPL Hair Remover has a light intensity of 2.0 J/cm^2 to 4.5 J/cm^2 and the predicate has a maximum optical of 3-6 J/cm^2. The Lumilisse IPL Hair Remover automatically controls the repetition rate for Level1, 1 pulse every 1.6 seconds and Level 5, 1 pulse every 3.5 seconds, whereas, the predicate states their repetition rate as manually, 1 pulse every 1-2 seconds. The differences in wavelength, light intensity and repetition rate raise no new issues of safety and effectiveness.

Predicate Product Comparison Table

Parameters	Conair Lumilisse IPL Hair Remover	Home Skinovations Ltd Silk'n Flash N Go	Syneron Beauty Ltd. mē	CyDen Ltd	Comments
510 (k) Number4		K103184	K131649	K160968	
Indications for Use	The Lumilisse IPL (Intense Pulsed Light) Hair Remover is an over-the-counter device intended for the removal of unwanted hair.	Flash N Go is an over the counter device intended for the removal of unwanted hair. Flash N Go is also intended for permanent reduction in hair regrowth defined as long-term, stable reduction in hair counts following a treatment regime.	The mē Is an over-the-counter device Intended for the removal of unwanted hair. Mē Is also Intended for permanent reduction 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.	Substantially Equivalent

Use Environment	Home Use	Home Use	Home Use	Home Use	Substantially Equivalent
Wavelength	550-1200 nm (when using with body lens) 600-1200 nm (when using with facial lens)	475-1200 nm	550-1200 nm	510-1100nm	Different
Light Intensity	Level 1: 2.0 J/cm^2 Level 2: 3.0 J/cm^2 Level 3: 3.5 J/cm^2 Level 4: 4.0 J/cm^2 Level 5: 4.5 J/cm^2	Level 1: 3-5 J/cm^2	Maximum Optical = 4 J/cm^2	3 – 6 J/cm^2	Different
Repetition Rate	At Level 1, 1 pulse every 1.6 seconds At Level 5, 1 pulse every 3.5 seconds	1 pulse every 3.5 seconds	1 pulse every 0.9 seconds	Manually, 1 pulse every 1-2 seconds	Different
Power Source	100-240 VAC, 3.5 A	100-240V, 2A	100-240 VAC, 50-60 Hz	110V or 230V, 50/60Hz	Substantially Equivalent
		Temperature			
Operating	+10°C to +35°C	10°C to 40°C	10°C - 30°	15°C - 30°C	Substantially Equivalent
Storage	-40°C to +70°C	-40°C to +70°C	10°C - 55°C	85% non-condensing	
		Humidity			
Operating	30% to 75% RH	30% to 75% RH	Up to 80% at 37°C	N/A	Substantially Equivalent
Storage	30% to 75% RH	30% to 90% RH	90% at 55°C	N/A	
		Atmospheric Pressure			
Operating	700 to 1060hPa	700 to 1060hPa	700-1060hPa	N/A	Substantially Equivalent

Non-clinical Performance Data:

- ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-1-11 Medical Electrical Equipment - Part 1-11: General Requirements for basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment
- 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 and cosmetic/aesthetic use.
- IEC 62471 **Photobiological safety of lamps and lamp systems**
- FCC Subpart 15B Unintentional Radiators
- ISO 14971 Medical Devices – Applications of Risk Management to Medical Devices
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "Moderate" level of concern.

Usability Study

A Human Factors Usability study was conducted using 20 participants to demonstrate the participants were capable of reading the instruction manual and were then able to use the Lumilisse IPL Hair Remover correctly. The Conair Lumilisse IPL Hair Remover was found to be safe and effective for the intended users, uses and use environments based on the results of our simulated use study, biocompatibility testing,

Clinical Study:

A clinical study was conducted comparing the G920 and G930 IPL Hair Remover (European pre-cursor to the IPL960F Lumilisse Hair Remover) hand-held systems to evaluate the in-vivo efficacy and cutaneous acceptability on the legs and cutaneous acceptability for the underarms and half-upper lips.

Each of the two units had a significant effect in lowering the amount and density of hairs in regions tested. The only safety events appear to be unrelated to the units, themselves. The dermatological evaluation was positive for safety, and the final study results, for the large majority of the test Subjects, was that the units had the desired effects.

The comparative study concluded the Lumilisse Hair Remover reduction results last for 6 months with over 75% less hair on legs and concluded cutaneous acceptability for legs, underarms and half-upper lip.

The study concluded Lumilisse Hair Removal Systems as safe and effective when used according to instructions.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Conair concludes that the Lumilisse IPL Hair Removal System is substantially equivalent to predicate devices with regard to safety and effectiveness.