December 23, 2025

Philips Consumer Lifestyle B.V.
% Shaylee Masilunas
Sr. Regulatory Affairs Project Manager
Philips Personal Health, Philips North America, LLC
1600 Summer St.
5th Floor
Stamford, Connecticut 06905

Re: K253754
Trade/Device Name: Philips Lumea IPL
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: November 25, 2025
Received: November 25, 2025

Dear Shaylee Masilunas:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 MACIOS -S
Digitally signed by MARK MACIOS -S
Date: 2025.12.23 12:36:05 -05'00'

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253754

Please provide the device trade name(s).

Philips Lumea IPL

Please provide your Indications for Use below.

Philips Lumea IPL is indicated for the removal of unwanted hair for a single user. It 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.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PHILIPS

510(k) Summary - K253754

(As required by 21CFR807.92)

I. SUBMITTER

Submission type	Special 510(k)
Company Name and Address	Philips Consumer Lifestyle B.V. Tussendiepen 4 9206 AD Drachten The Netherlands
Primary Correspondent/Consultant Information	Mrs. Shaylee Masilunas Sr. Regulatory Affairs Project Manager Email: shaylee.masilunas@philips.com
Contact Person	Mr. Martijn Halbesma Group Lead G&B Regulatory & Compliance Email: pclcerts@philips.com
Date Prepare	24 November 2025

II. SUBJECT DEVICE

Trade Name	Philips Lumea IPL
Classification Regulation	21CFR§878.4810
Regulation Description	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Product Code	OHT: Light Based Over-The-Counter Hair Removal, GEX: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology (subsequent product code)
Device Classification	2
Regulation medical specialty	General & Plastic Surgery
Premarket review	Office of Surgical and Infection Control Devices

III. PREDICATE DEVICE

Trade Name	Philips Lumea IPL (K243453)
Classification Regulation	21CFR§878.4810
Regulation Description	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Product Code	OHT: Light Based Over-The-Counter Hair Removal, GEX: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology (subsequent product code)
Device Classification	2
Regulation medical specialty	General & Plastic Surgery
Premarket review	Office of Surgical and Infection Control Devices

IV. DEVICE DESCRIPTION

Philips Lumea IPL is an Intense Pulsed Light (IPL) device intended for removal of unwanted hair. The device is to be used by persons in the age range of 18-65 years with fair up to medium brown skin tones, and naturally dark blond, brown, dark brown and black hair.

The Philips Lumea IPL applies spectrally adjusted light to the user skin, which is absorbed by the melanin and after some applications hair sheds naturally and growth is delayed or inhibited.

The Philips Lumea IPL is an Over-the-counter hand-held device powered by a wall mount adapter. It is provided in a non-sterile state and intended to be used by single person for multiple uses in homecare environment.

V. INDICATIONS FOR USE

Philips Lumea IPL is indicated for the removal of unwanted hair for a single user. It 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The table below provides a side-by-side comparison of the subject device and predicate device. The difference between the subject device and the predicate device are outlined in Table 1.

Table 1: Feature / Characteristics comparison of Subject device and Predicate device

Feature / Characteristic for comparison	Subject Device - Philips Lumea IPL (9900 Pro)	Predicate Device – Philips Lumea IPL (K243453)	Similarity between Subject and Predicate Device
Classification			
Legal Manufacturer	Philips Consumer Lifestyle B.V.	Philips Consumer Lifestyle B.V.	Identical
510(k) Number	In this application	K243453	Not applicable
Device Regulation	21CFR878.4810	21CFR878.4810	Identical
Classification Product Code	OHT, GEX (Subsequent Product Code)	OHT, GEX (Subsequent Product Code)	Identical
Device Classification Name	OHT: Light Based Over-The-Counter Hair Removal	OHT: Light Based Over-The-Counter Hair Removal	Identical
	GEX: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology	GEX: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology	Identical
Device Class	2	2	Identical
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	Identical
Indications for Use			
Indications for Use	Philips Lumea IPL is indicated for the removal of unwanted hair for a single user. It 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.	Philips Lumea IPL is indicated for the removal of unwanted hair for a single user. It 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.	Identical
Operating Environment Characteristics			
Availability	Over-The-Counter Use (21 CFR 801 Subpart C)	Over-The-Counter Use (21 CFR 801 Subpart C)	Identical
Intended User Group	18 to 65 Years	18 to 65 Years	Identical
Treatment Areas	**Skin tone:** The device is intended for use on fair up to medium brown skin tones.	**Skin tone:** The device is intended for use on fair up to medium brown skin tones.	Identical
	Hair color: Naturally dark blond, brown, dark brown and black hair	**Hair color:** Naturally dark blond, brown, dark brown and black hair	Identical
Reusability	Single Patient Multiple Use	Single Patient Multiple Use	Identical
Environment of Use	Home	Home	Identical

Feature / Characteristic for comparison	Subject Device - Philips Lumea IPL (9900 Pro)	Predicate Device – Philips Lumea IPL (K243453)	Similarity between Subject and Predicate Device
Operating Environment	Temperature range: 5°C to 40°C (41°F to 104°F)	Temperature range: 5°C to 40°C (41°F to 104°F)	Identical
	Relative humidity range: 15% to 90% RH (noncondensing)	Relative humidity range: 15% to 90% RH (noncondensing)	Identical
	Atmospheric pressure range: 700hPa to 1060hPa.	Atmospheric pressure range: 700hPa to 1060hPa.	Identical
Storage and Transport Environment	Temperature range: -25°C to 70°C (-13°F to 158°F)	Temperature range: -25°C to 70°C (-13°F to 158°F)	Identical
	Relative humidity: upto 95% RH (noncondensing)	Relative humidity: upto 95% RH (noncondensing)	Identical
	Atmospheric pressure range: 700hPa to 1060hPa	Atmospheric pressure range: 700hPa to 1060hPa	Identical
Technology & Safety Characteristics			
Operating Principle	Intense pulsed light hair removal	Intense pulsed light hair removal	Identical
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Identical
Power Source	External power supply	External power supply	Identical
User Interface	Flash Button LED indicators	Flash Button LED indicators	Identical
Safety Features	Skin detection Sensor	Skin detection Sensor	Identical
	Skin tone detection Sensor	Skin tone detection Sensor	Identical
Wireless Connectivity	Bluetooth Low Energy (BLE) (Wireless connection with Mobile App – Lumea)	No connectivity available (No connection with Mobile App – Lumea)	**Equivalent**
Real-time motion guidance	Real-time motion guidance using Inertial Measurement Unit (IMU) Sensor	No motion sensing available	**Equivalent**
Over-the-air software updates	Yes	No	**Equivalent**
Software / Firmware / Microprocessor control	Yes	Yes	Identical
Performance Specifications			
# of Attachments	Body Attachment Face Attachment Precision Attachment	Body Attachment Face Attachment Precision Attachment	Identical
Spot Size (cm^2)	Body Attachment: 4.1 cm^2	Body Attachment: 4.1 cm^2	Identical
	Precision Attachment: 3 cm^2	Precision Attachment: 3 cm^2	
	Face Attachment: 2 cm^2	Face Attachment: 2 cm^2	
Emitted Light Spectrum (nm)	520nm - 1200nm (max.)	520nm - 1200nm (max.)	Identical
Energy Density (J/cm^2)	6 J/cm^2 (Max)	6 J/cm^2 (Max)	Identical
Pulse duration	1.25±0.4 ms (FWHM)	1.25±0.4 ms (FWHM)	Identical
Optical Pulse Interval	0.6 - 2.4 s	1.0 - 2.4 s	**Equivalent**
Electrical System Characteristics			
Supply Frequency	50/60 Hz.	50/60 Hz.	Identical
Supply Voltage	100-240 VAC	100-240 VAC	Identical
International Standards			
IEC 60601-1	Yes	Yes	Identical
IEC 60601-1-2	Yes	Yes	Identical
IEC 60601-1-6	Yes	Yes	Identical
IEC 60601-1-11	Yes	Yes	Identical
IEC 62366-1	Yes	Yes	Identical
IEC 62304	Yes	Yes	Identical
IEC 60601-2-57	Yes	Yes	Identical

Feature / Characteristic for comparison	Subject Device - Philips Lumea IPL (9900 Pro)	Predicate Device – Philips Lumea IPL (K243453)	Similarity between Subject and Predicate Device
IEC 60601-2-83	Yes	Yes	Identical
ISO 10993-1	Yes	Yes	Identical
ISO 10993-5	Yes	Yes	Identical
ISO 10993-10	Yes	Yes	Identical

VII. PERFORMANCE DATA

Summary of non-clinical tests

The Philips Lumea IPL has been tested to the applicable requirements of the following standards:

Standards and Designation Number	Standards Title
ANSI/AAMI ES60601-1:2005/A2:2021	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance - Amendment 2
ANSI/AAMI IEC 60601-1-2:2014 + A1:2021	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
IEC 60601-1-6:2010 + A1:2013 + A2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ANSI AAMI IEC 60601-1-11:2015 + A1:2021	Medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-2-83:2019 + A1:2022	Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
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
ISTA 3A: 2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
ANSI AAMI IEC 62304 2006 + A1:2016	Medical device software — Software life cycle processes
IEC 82304-1 ed.1 2016-10	Health Sofware – Part 1: General requirements for product safety
IEC 81001-5-1 ed.1.0 2021-12	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle
ANSI AAMI IEC 62366-1:2015 + A1:2020	Medical devices — Part 1: Application of usability engineering to medical devices
ANSI AAMI ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ANSI AAMI ISO 10993-5:2009/(R)2014	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021-11	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

Software verification and validation testing were conducted and basic level of documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions (2023)."

VIII. CONCLUSIONS

Philips concludes that the supporting information and justifications provided herein conclusively demonstrate that the subject device, Philips Lumea IPL (9900 Pro) is substantially equivalent to the predicate device, Philips Lumea IPL (K243453).