



September 30, 2026

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

Re: K261975

Trade/Device Name: Braun Aura 7 (6041)

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: September 16, 2026

Received: September 16, 2026

Dear Matthew Silverberg:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

TANISHA
L. HITHE -S

Digitally signed by
TANISHA L. HITHE -S
Date: 2026.09.30
19:50:41 -04'00'

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.

K261975

?

Please provide the device trade name(s).

?

Braun Aura 7 (6041)

Please provide your Indications for Use below.

?

The Braun Aura 7 is intended for the removal of unwanted hair. The Braun Aura 7 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](#))

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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. Matthew Silverberg
Applicant Contact Email	msilverberg@cyden.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Braun Aura 7 (6041)
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
K243362	SmoothSkin Pure Switch (SSC1)	OHT
k143003	iPulse SmoothSkin Gold Hair Removal System	OHT, ONX, GE ₊

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The 6041 device is an over the counter IPL (Intense Pulsed Light) Hair Removal device for home use.

The device is mains powered and consists of the handset, hardwired base unit and AC power cord. AC mains is fed into the AC to DC converter that 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 Braun Aura 7 is intended for the removal of unwanted hair. The Braun Aura 7 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 6041 device has the same following characteristics.

- The same intended use.
- Operates with the same mode of actions.
- Has the same technological characteristics.
- 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 modification have been made to the SSC1 device.

- Aesthetic changes.
- Addition of the Autoflash firing mode.

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 : 2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- 2) IEC 60601-1-6 : 2010 +AMD1:2013 +AMD2:2020 Medical Electrical Equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- 3) IEC 60601-2-83 : 2019 +AMD1:2022 Medical Electrical Equipment: Part 2-83: Particular requirement for the basic safety and essential performance of home light therapy equipment
- 4) IEC 60601-1-2 : 2014+A1:2021 Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- 5) IEC 62471: 2006 Photobiological safety of lamps and lamp systems

The device is compliant with the following Biocompatibility standards

- 1) ISO 10993-1 : 2009, Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- 2) ISO 10993-5 : 2009, Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- 3) ISO 10993-10 : 2010, Biological evaluation of medical devices Part 10: Tests for skin sensitization

The Braun Aura 7 (6041) has the same intended use, mode of action and similar operational characteristics as the predicate device. Therefore the Braun Aura 7 (6041) is found substantially equivalent to its predicate devices.