



September 10, 2025

Pollogen Ltd.  
% Elissa Burg  
Regulatory Consultant  
BioVision Ltd.  
Perach Halilach Street 183  
Had Nes, 1295000  
Israel

RE: K250734

Trade/Device Name: OptiLUV Device  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: PBX  
Dated: August 11, 2025  
Received: August 11, 2025

Dear Elissa Burg:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Colin K.  
Chen -S** Digitally signed by  
Colin K. Chen -S  
Date: 2025.09.10  
14:40:45 -04'00'

Colin Kejing Chen, Ph.D.  
Acting 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

Submission Number (if known)

K250734

Device Name

OptiLUV Device

Indications for Use (Describe)

The OptiLUV device is a handheld device intended to emit energy in the RF spectrum to provide topical heating for the purpose of elevating facial tissue temperature for a temporary relief of minor pain and the temporary increase in local blood circulation.

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.**

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

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**510(k) SUMMARY - K250734**  
**Pollogen Ltd.'s OptiLUV Device**

**Applicant:** Pollogen Ltd.  
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**Contact Person:** Elissa Burg  
Regulatory Consultant  
BioVision Ltd.  
Had Nes 183  
Israel 1295000  
Tel. (972) 526633572

**Date Prepared:** September 8, 2025

**Device Name:** OptiLUV Device

**Common Name:** Electrosurgical cutting and coagulation device and accessories

**Classification:** **Product Codes:** PBX, GEI  
**Regulation No:** 21 CFR §878.4400  
**Class:** II  
**Classification Panel:** General and Plastic Surgery

**Predicate Device** EL Global Trade Ltd. RF-Relief device (K181095)  
**Reference Device** Pollogen Ltd. STOP U (K140255)

**Intended Use/Indications for Use**

The OptiLUV device is a handheld device intended to emit energy in the RF spectrum to provide topical heating for the purpose of elevating facial tissue temperature for a temporary relief of minor pain and the temporary increase in local blood circulation.

## Device Description

The OptiLUV device is a non-invasive, non-ablative device that delivers RF energy into the skin to generate heat through electrical impedance in the dermis. The device consists of the following components and accessories: the OptiLUV device, the USB Charging Cord, and the OptiLUV Preparation Balm.

## Technological Characteristics

The OptiLUV device delivers RF energy at a frequency of 1 MHz and a maximum output power of 1.8 watts into the skin through its electrodes. The device generates heat through electrical impedance in the dermis. The temperature sensor, located between the electrodes, constantly monitors the skin temperature and disables RF transmission once the maximum allowed skin temperature ( $41.5 \pm 1$  °C) is obtained.

## Summary of Non-clinical and/or Clinical Tests

Pollogen conducted several performance tests to demonstrate that the OptiLUV Device complies with appropriate consensus standards and that it functions as intended.

- OptiLUV's power accuracy testing was performed to verify that the power levels are within the predefined acceptance criteria.
- OptiLUV's overheating safety testing was performed to verify the proper function and accuracy of the safety mechanism, while the temperature sensor constantly measures the skin temperature during treatment and deactivates RF transmission once the maximal allowed skin temperature is obtained.
- The OptiLUV software was validated as required.

In all instances, the OptiLUV Device functioned as intended, and observations were as expected.

The OptiLUV Device complies with the following consensus standards:

- ISO 14971:2019, Ed.3 - Medical devices – Application of risk management to medical devices.
- IEC 60601-1:2005+ AMD1:2012 + AMD2:2020, Ed. 3.2 - Medical Electrical Equipment Part 1: General requirements for safety.

- IEC 60601-1-2: 2014 + AMD1:2020, Ed. 4.1 - Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-2-2: 2017 + AMD1:2023, Ed.6.1 - Medical Electrical Equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.
- IEC TS 60601-4-2: 2024, Ed. 1.0 - Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.
- IEC 60601-1-11: 2015 + AMD1:2020, Ed.2.1 - 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 (. 2015 and AMD2:2020 (ed.2.1)
- IEC 60601-1-6: 2010+AMD1:2013+AMD2:2020, Ed.3.2 Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
- IEC 62366-1: 2015+AMD1:2020, Ed. 1.1 - Medical devices - Part 1: Application of usability engineering to medical devices.
- ISO 10993-1:2018, Ed.5 - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- IEC 62304: 2006+AMD A1:2015, Ed.1.1 - Medical device software – Software life cycle processes.
- ANSI/AAMI ST98:2022 Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices.
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems.
- ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing.

## **Clinical Testing**

The OptiLUV device was evaluated in a clinical study to demonstrate that its RF output power of 1.8 watts has the ability to maintain the desired safe and effective treatment temperature on the surface of human skin throughout a treatment duration of 10 minutes.

No adverse events were observed or reported during the course of this study.

The clinical trial results confirm that the OptiLUV device is safe and effective for its intended use.

**Substantial Equivalence Comparison**

The following table provides a comparison of the OptiLUV Device to its predicate and reference devices, addressing intended use, technological characteristics, and principles of operation to support the substantial equivalence determination.

<b>Feature</b>	<b>OptiLUV Proposed Device</b>	<b>RF-Relief (K181095) Predicate Device</b>	<b>STOP U (K140255) Reference Device</b>
<b>Manufacturer</b>	Pollogen Ltd.	EL Global Trade Ltd	Pollogen Ltd.
<b>Device Class</b>	Class II	Class II	Class II
<b>Classification Panel</b>	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
<b>Product Code</b>	PBX, GEI	GEI, PBX	GEI
<b>Regulation Number</b>	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
<b>Regulation Description</b>	<ul style="list-style-type: none"> <li>• Massager, Vacuum, Radio Frequency Induced Heat</li> <li>• Electrosurgical cutting and coagulation device and accessories</li> </ul>	<ul style="list-style-type: none"> <li>• Massager, Vacuum, Radio Frequency Induced Heat</li> <li>• Electrosurgical cutting and coagulation device and accessories</li> </ul>	<ul style="list-style-type: none"> <li>• Electrosurgical cutting and coagulation device and accessories</li> </ul>
<b>Intended use</b>	The OptiLUV device is a handheld device intended to emit energy in the RF spectrum to provide topical heating for the purpose of elevating facial tissue temperature for a temporary relief of minor pain and the temporary increase in local blood circulation.	The RF-Relief is an over the counter hand held device intended to emit energy in RF spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and temporary relaxation of muscles.	Pollogen's STOP U is intended for use in the non-invasive treatment of mild to moderate facial wrinkles and rhytides.
<b>Mode of Operation</b>	RF energy emitted from multiple bipolar electrodes via a delivery handpiece	RF energy emitted from multiple bipolar electrodes via a delivery handpiece	RF energy emitted from multiple bipolar electrodes via a delivery handpiece

Feature	OptiLUV Proposed Device	RF-Relief (K181095) Predicate Device	STOP U (K140255) Reference Device
Treatment area	Face	Treatment area not specified	Face
Energy source	RF (Bipolar)	RF (Bipolar)	RF (Bipolar)
Frequency	1±0.05 MHz	1±0.05 MHz	1±0.05 MHz
Number of electrodes	4 electrodes (2 pairs)	4 electrodes (2 pairs)	4 electrodes (2 pairs)
Intended population	Adult Users	Adult Users	Adult Users
Use environment	Prescription Use – Rx Only	Home Use, OTC- self-operation by an untrained user.	Prescription Use – Rx Only
Energy source	RF (Bipolar)	RF (Bipolar)	RF (Bipolar)
Energy levels	1.8 watts 1 energy level: 1.8 watts	Up to 10 watts 3 energy levels: 6, 8 or 10 watts	5.7 watts 1 energy level: 5.7 watts
Safety mechanism	Thermal sensor for skin temperature measurements	Thermal sensor for skin temperature measurements	Thermal sensor for skin temperature measurements
Electrical requirements	100-240 V 50-60 Hz	100-240 V 50-60 Hz	100-240 V 50-60 Hz
Safety/EMC	<ul style="list-style-type: none"> <li>• IEC 60601-1</li> <li>• IEC 60601-1-2</li> <li>• IEC 60601-2-2</li> <li>• IEC 60601-1-11</li> </ul>	<ul style="list-style-type: none"> <li>• IEC 60601-1</li> <li>• IEC 60601-1-2</li> <li>• IEC 60601-2-2</li> <li>• IEC 60601-1-11</li> </ul>	<ul style="list-style-type: none"> <li>• IEC 60601-1</li> <li>• IEC 60601-1-2</li> <li>• IEC 60601-2-2</li> <li>• IEC 60601-1-11</li> </ul>
Non-sterile reusable	Non-sterile Reusable	Non-sterile Reusable	Non-sterile Reusable
Biocompatibility	All parts that are in contact with user comply with the requirements of ISO-10993-1.	All parts that are in contact with user comply with the requirements of ISO-10993-1.	All parts that are in contact with user comply with the requirements of ISO-10993-1.
Software	The software was verified and validated according to the FDA guidance.	The software was verified and validated according to the FDA guidance.	The software was verified and validated according to the FDA guidance.

**Conclusion**

The OptiLUV and the predicate device have the same intended use/indications for use and similar technological characteristics and principles of operation. The differences between the OptiLUV Device and its predicate do not raise new concerns of safety or effectiveness, as demonstrated by comparative bench performance testing and clinical study. Based on the totality of evidence, the OptiLUV Device is found substantially equivalent to the predicate device.