April 14, 2025

Elfi-Tech Ltd.
Orly Maor
Regulatory consultant
150 Derech Menachem Begin
Tel Aviv, 6492105
Israel

Re: K243852
Trade/Device Name: Elfor-L
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: December 12, 2024
Received: December 16, 2024

Dear Orly Maor:

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.04.14 17:03:18 -04'00'

Tanisha Hithe
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243852

Device Name
Elfor-L

Indications for Use *(Describe)*
The Elfor L is intended for measuring micro-vascular perfusion in skin and muscle in humans. It is intended to be used for clinical research applications and pre clinical research applications.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

Traditional Premarket Notification Submission – 510(k)
Elfor-L
510(k) Number _____

Date Prepared: December 12, 2024

I. SUBMITTER
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II. DEVICE
Name of Device: Elfor-L
Common or Usual Name: Elfor-L
Classification Name: 21CFR 870.2100- Cardiovascular blood flowmeter
Regulatory Class: II
Product Code: DPW

III. PREDICATE DEVICE
ELFI-TECH Ltd. believes that Elfor-L is substantially equivalent to the following predicate device:

- Perimed Inc. PeriFlux 5000 cleared under K974285, Product code DPW, Regulation number 21 CFR 870.2100 and in subsequent submission under K152930, PeriFlux 6000, Product code DPW, Regulation number 21 CFR 870.2100.

IV. DEVICE DESCRIPTION
The Elfor-L device is making use of Miniaturized Dynamic Light Scattering (mDLS) technology to non-invasively measure micro-vascular perfusion in the skin. The device is comprised of sensor and signal processing station. The device uses Vertical-Cavity Surface-Emitting Lasers (VCSEL) as the light source and two photodetectors for detection.

The Elfor-L design incorporates three major components.

1. Sensor- the sensor as its predicate includes a laser light source and two photo sensitive elements. The sensor transfers analog signal to the control unit.
2. Control unit - the control unit is connected to the sensor by cable and includes the control circuit for the sensor, microcontroller and communication interface for the PC.
3. Dedicated software that processes, displays and record data on the computer. The computer is not part of the system.

V. INDICATIONS FOR USE

The Elfor-L is intended for measuring microvascular perfusion in skin and muscle in humans. It is intended to be used for clinical research applications and pre-clinical research applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Elfor-L has the same intended use as the predicate device. Its indications for use are identical to that of the predicate device.

The Elfor-L has similar technological characteristics as the predicate device as demonstrated in the table below:

	ELFOR-L	**PERIFLUX 5000**	**PERIFLUX 6000**	**SE JUSTIFICATION**
510(k) Number	TBD	K974285	K152930	**___**
Manufacturer	ELFI-TECH	Perimed AB	Perimed AB	**___**
Product Code	DPW	DPW	DPW	**Same**
CFR	870.2100	870.2100	870.2100	**Same**
Intended Use	The Elfor L is intended for measuring micro-vascular perfusion in skin and muscle in humans. It is intended to be used for clinical research applications and pre-clinical research applications.	The PF 5010 LDPM Unit is indicated for use in measuring micro-vascular perfusion in skin and muscle in humans. It is also intended for use in measuring micro-vascular perfusion in all tissues in animals.	PeriFlux 6000, equipped with PF 6010 is intended for measuring micro-vascular perfusion in skin and muscle in humans. It is also intended for measuring micro-vascular perfusion in all tissues in animals for research purposes.	**Same**

	ELFOR-L	PERIFLUX 5000	PERIFLUX 6000	SE JUSTIFICATION
Intended User	The Elfor-L is intended for professional use in a hospital environment, laboratory environment and in a hospital intensive care unit environment.	The PF 5010 LDPM Unit is intended for professional use in a hospital environment, laboratory environment and in a hospital intensive care unit environment.	The PeriFlux 6000 instrument is intended for professional use in a hospital environment, laboratory environment and in a hospital intensive care unit environment.	**Same**
Patient Population	The Elfor-L can be used for measurements on patients of all ages.	The PF 5010 LDPM Unit can be used for measurements on patients of all ages.	The PF 6010 LDPM/Temp Unit can be used for measurements on patients of all ages.	**Same**
Body contact	The Elfor-L is intended for measurements on intact skin.	The PeriFlux 5000 is intended for measurements on intact skin.	The PeriFlux 6000 is intended for measurements on intact skin.	**Same**
Maximum laser current	3-5mA	Not specified.	5mA	**Within the predicate range**
Laser product classification	Class I laser product per IEC 60825-1.	Class I laser product per IEC 60825-1.	Class I laser product per IEC 60825-1.	**Same**
Laser Type	Invisible, near-infrared, 850nm	Invisible, near-infrared 780 nm	Invisible, near-infrared, 785nm	**Similar**
Perfusion measurement	0-2000 PU	Upper limit not specified.	0–2000 PU	**Same as PeriFlux 6000**
Perfusion Accuracy	250±10	Motility standard: 250±20 PU Zeroing disc: 0.0±1.0 PU	± 2 PU at zero, ±4 % in motility standard	**Same**
Signal Bandwidth	5Hz -24KHz	20 Hz to 15 kHz	5 Hz - 25 kHz	**Substantially equivalent**
Calibration	Required	Required.	Required	**Same**
List of main components	1. VCSEL laser source 2. Two photodetectors 3. Amplifier 4. Current driver 5. A2D convertor 6. Microprocessor Adhesive Tape and Disposable patches	1. Laser source 2. Fiber optic probe 3. Photodetector 4. Amplifier 5. A2D convertor 6. Microprocessor Adhesive Tape and Probe holder	1. Laser source 2. Fiber optic probe 3. Photodetector 4. Amplifier 5. A2D convertor 6. Microprocessor Adhesive Tape and Probe holder	**Similar**

	ELFOR-L	PERIFLUX 5000	PERIFLUX 6000	SE JUSTIFICATION
Power source	The Elfor-L receives its power from a USB port (5V; 0.5A)	100–240 Volts, 50 or 60 Hz.	100–240 Volts, 50 or 60 Hz.	**Different however, no safety issue**
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60825-1	**Same**

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- **Biocompatibility**

  Biocompatibility evaluation in compliance with ISO 10993-1 was performed.
  The following tests were conducted:
  Cytotoxicity Study Using the ISO Elution Method
  ISO Guinea Pig Maximization Sensitization Test
  ISO Intracutaneous -irritation Study in Rabbits
  The device was found biocompatible.

- **Performance Testing**

  Performance testing included comparison testing of the Elfor-L to its predicate device. The main purpose of this test was to verify the Elfor-L performance is similar to that of its predicate.
  The test passed and met the predefined acceptance criteria.

  Accuracy of the Elfor-L device- the purpose of this test was to evaluate the accuracy of the Elfor-L by repeated measurements using a standardized Motility Standard solution. The test passed.

- **Software Validation**

  Software verification and validation testing of the Elfor-L were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions".

- **Electrical Safely and EMC**

  Electrical Safety per IEC 60601-1, Electromagnetic compatibility (EMC) per IEC 60601-1-2, IEC 60601-4-2 and IEC 60825-1 were conducted on the Elfor-L. The tests passed.

VIII. CONCLUSION

The Elfor-L was determined to be substantially equivalent to the predicate device.