October 28, 2026

Lymphatech, Inc.
% Grace Powers
Founder/ Principal Consultant
Powers Regulatory Consulting
2451 Cumberland Pkwy. SE
Suite 3740
Atlanta, Georgia 30339

Re: K261628
Trade/Device Name: LymphaTech Mobile 3D Measuring Tool
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: Class II
Product Code: OBH, SFG
Dated: October 1, 2026
Received: October 1, 2026

Dear Grace Powers:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely, MAURA ROONEY -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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.	K261628

Please provide the device trade name(s).

LymphaTech Mobile 3D Measuring Tool

Please provide your Indications for Use below.

The LymphaTech Mobile 3D Measuring Tool is a software application that uses input from the Structure Sensor, an off-the-shelf long-wave infrared camera, to measure the diameter, surface area, volume, and perimeter/circumference of a part of the body. The 3D Measuring Tool is non-contact with respect to the patient and provides an adjunctive tool to help a qualified health care professional measure and record body part data. The device uses input from the Structure Sensor camera to accurately capture and construct a 3D model of a patient's anatomy. It is intended for trained and qualified healthcare professionals, who are trained in its use. The 3D Measuring Tool is to be used on a patient population that includes non-pregnant female or male adults. The 3D Measuring Tool is intended to be used in any environment where health care is provided by a qualified health care professional. The LymphaTech Mobile 3D Measuring Tool provides circumference and volume measurements of a part of the body to aid in the assessment of lymphedema in patients with lymphedema, or patients at risk for developing lymphedema. The 3D Measuring Tool does not provide a diagnosis or therapy.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the LymphaTech Traditional 510(k) premarket notification.

Sponsor: LymphaTech

Submission Contact: Grace Powers, FRAPS, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
grace@powersregulatory.com

Submission Date: May 15, 2026

Subject Device: Trade Name: LymphaTech Mobile 3D Measuring Tool
Common Name: Tape, Camera, Surgical and Impedance Plethysmograph
Classification Name: Surgical camera and accessories and Monitor, Extracellular fluid, Lymphedema, Extremity
Regulation: 21 CFR 870.2770, 21 CFR 878.4160,
Regulatory Classification: Class II
Product Code: OBH, SFG.

Predicate Device: SOZO Body Fluid Analyzer (K180126)
Reference Device: LymphaTech Mobile 3D Measuring Tool (K251255)

Device Description

The LymphaTech Mobile 3D Measuring Tool is a standalone software mobile application that uses a high-accuracy off-the-shelf long-wave infrared camera for measuring the diameter, surface area, volume, and perimeter of a part of the body. The LymphaTech Mobile 3D Measuring Tool provides circumference and volume measurements of a part of the body to aid in the assessment of lymphedema in patients with lymphedema, or patients at risk for developing lymphedema. The software allows clinicians to measure body region volume, circumference, surface area, and length with high precision. Specifically, this device uses an off-the-shelf depth sensing scanner, which is a type of long-wave infrared camera, together with an off-the-shelf iPad to acquire complete 3D renderings of the body regions.

Intended Use/Indications for Use

The LymphaTech Mobile 3D Measuring Tool is a software application that uses input from the Structure Sensor, an off-the-shelf long-wave infrared camera, to measure the diameter, surface area, volume, and perimeter/circumference of a part of the body. The 3D Measuring Tool is non-contact with respect to the patient and provides an adjunctive tool to help a qualified health care professional measure and record body part data. The device uses input from the Structure Sensor camera to accurately capture and construct a 3D model of a patient's anatomy. It is intended for trained and qualified healthcare professionals, who are trained in its use. The 3D Measuring Tool is to be used on a patient population that includes non-pregnant female or male adults. The 3D Measuring Tool is intended to be used in any environment where health care is provided by a qualified health care professional. The LymphaTech Mobile 3D Measuring Tool provides circumference and volume measurements of a part of the body to aid in the assessment of lymphedema in patients with lymphedema, or patients at risk for developing lymphedema. The 3D Measuring Tool does not provide a diagnosis or therapy.

Substantial Equivalence

An overview comparison of the LymphaTech Mobile 3D Measuring Tool (subject device) compared to the predicate device (K180126) is presented in the table below. The reference device (LymphaTech Mobile 3D Measuring Tool) uses the same high-accuracy off-the-shelf long-wave infrared camera for a different intended use. The subject device is based on the same optical scanning platform and software architecture as the previously cleared LymphaTech Mobile 3D Measuring Tool (K251255). With the exception of the updated Indications for Use specifying that circumference and volume measurements are provided to aid in the assessment of lymphedema, the subject device is identical to the reference device in terms of hardware configuration, measurement technology, scan acquisition workflow, software architecture, data handling, cybersecurity controls, and baseline human factors design.

Table 1: Device Comparison

		Subject Device: LymphaTech Mobile 3D Measuring Tool	**Predicate Device: SOZO (K180126)**	**Comparison**
Regulatory information	Manufacturer	LymphaTech	Impedimed	N/A
	Product Code	OBH, SFG	OBH	Similar- Both the predicate reference device product codes are listed.
	Device Classification Name	Camera, Surgical, Measurement and Impedance plethysmograph	Impedance Plethysmograph	Different – Both classification names are listed.
	Device Classification	Class II	Class II	Identical.
	Indication for Use	See above.	The SOZO body fluid analyzer has the following uses: For adult human patients at risk of lymphedema: A bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of lymphedema. The use of the device to obtain an L-Dex score is only	Similar- Both devices provide objective quantitative measurement information used by trained healthcare professionals as an adjunct tool to support clinical assessment of lymphedema and do not provide a stand-alone diagnosis or therapy.

		Subject Device: LymphaTech Mobile 3D Measuring Tool	Predicate Device: SOZO (K180126)	Comparison
			indicated for patients who will have or who have had lymph nodes, from the axillary and/or pelvic regions, either removed, damaged or irradiated.	
	Rx or OTC	Rx Only	Rx Only	Identical.
Principles of Operation		Provides circumference and volume (and related geometric) measurements of body regions to aid a clinician's assessment of lymphedema; adjunctive measurement and record tool; no diagnosis/therapy.	Provides an L-Dex ratio/score (extracellular fluid volume difference indicator) as an aid to a clinician's clinical assessment of lymphedema in at-risk adults.	Similar- Both devices provide an objective quantitative output intended to support clinician assessment and longitudinal monitoring of lymphedema.
Setting of Use		Clinical environment where measurement can be conducted (facility/clinic).	Clinical environment where measurement can be conducted (facility/clinic).	Identical.
Intended Users		Trained and qualified healthcare professionals (Rx).	Healthcare professionals / clinicians (Rx).	Identical.
Patient population		Non-pregnant male or female adults; includes patients with lymphedema and adults at risk for developing lymphedema.	Adult human patients at risk of lymphedema (e.g., lymph node removal/damage/irradiation).	Similar- Both devices are intended for adult patient populations where lymphedema assessment and monitoring is clinically relevant.
Outputs relevant to lymphedema assessment		Volume and circumference metrics of a limb/body region;	L-Dex score representing extracellular fluid volume differences between limbs, longitudinal metric change.	Similar- Both devices provide an objective numeric output used for longitudinal

		Subject Device: LymphaTech Mobile 3D Measuring Tool	Predicate Device: SOZO (K180126)	Comparison
		longitudinal metrics change.		assessment of change over time to support clinician evaluation of lymphedema status.
Measurement Principle		3D surface capture and model reconstruction from a depth camera; computes geometric measures (circumference, volume, surface area, diameter).	Bioimpedance spectroscopy applying low-level current across multiple frequencies to estimate extracellular fluid volume and calculate L-Dex® ratio/score.	Different- The subject device uses structured light depth capture to reconstruct a 3D surface model and compute geometric measures, while the predicate uses multi-frequency bioimpedance spectroscopy.
Patient Contact		Non-patient contacting	Contact via stainless steel hand/foot electrodes.	Different.
Energy delivered to patient		None (imaging-only).	Very low electrical current applied through electrodes.	Different.
Key hazards driven by technology		Measurement error due to scan quality, positioning, motion; data handling/ security; workflow/ labeling risks.	Electrical safety/EMC; contact/biocompatibility; measurement error; data handling/security; workflow/labeling risks.	Similar.
Testing		Bench testing and clinical usability testing. Clinical study data was also used to support this submission.	Bench testing and clinical usability testing.	Similar.
Software and Connectivity	Storage of data	Electronically records and stores source data.	Electronically records and stores source data.	Identical.

		Subject Device: LymphaTech Mobile 3D Measuring Tool	Predicate Device: SOZO (K180126)	Comparison
	Device connectivity	None required. Measurements and images remain on iPad.	Measurements can be updated to electronic medical records and are stored in the cloud. Connects to a portal and EMR.	Different.
	Cybersecurity	LDAP authentication with Role Based Access Control (RBAC); local data storage with AES-256 encryption; device-level logging and auto-recovery functions; no cloud storage or external database communication.	Networked system with a supplied tablet paired to the hardware via Bluetooth and connectivity to a facility network database ("SOZOhub") over Wi-Fi, with electronic access and storage of measurement data through the local database infrastructure.	Similar.
Hardware	Hardware / system components	Off-the-shelf iPad, Structure Sensor (long-wave infrared depth camera), mounting hardware, and connection cable.	SOZO hardware consists of a connected hand and footplate with built-in stainless steel electrodes paired with a supplied Android tablet over Bluetooth; the tablet connects over Wi-Fi to the SOZOhub database hosted on a network-connected PC.	Different.
	Computing Device	Off-the-Shelf iPad running iPad iOS 14 or higher.	Supplied Android tablet + network-connected PC (SOZOhub).	Different.

Performance Testing

Performance testing of the subject device was conducted on humans to show usability and accuracy of the software. There are no device-specific guidance documents, special controls document, and/or requirements in a device-specific regulation that is applicable to the subject device.

A list of the testing for the LymphaTech Mobile 3D Measuring Tool is listed below:

- Software Verification Testing
- Cybersecurity Testing
- Usability Testing

- Bench Performance Testing

Two prospective clinical performance studies were conducted to evaluate the accuracy, reliability, and reproducibility of the subject device. The first study evaluated lower extremity measurements using water displacement as the reference method for volume and manual tape measurement as the reference method for circumference. The study also evaluated inter-operator variability across trained users. This study included both male and female subjects and therefore provides sex-based subgroup evidence.

The second study evaluated upper extremity measurements in female breast cancer patients with or at risk of developing lymphedema. LymphaTech measurements were compared to Perometer measurements for both volume and circumference, and volume reproducibility was evaluated using repeated measurements. This study included racially diverse subjects and included patients at risk of developing upper extremity lymphedema following breast cancer treatment. At-risk arms were evaluated as a distinct clinical subgroup to confirm that device performance was maintained not only in clinically affected arms, but also in arms under surveillance for potential lymphedema development. Together, these studies support the clinical performance of the LymphaTech Mobile 3D Measuring Tool for measuring limb volume and circumference within the intended-use population.

Conclusion

The LymphaTech Mobile 3D Measuring Tool is substantially equivalent to the legally marketed predicate device as demonstrated by the similar intended use, and does not raise different questions of safety or effectiveness and is supported by appropriate performance data and evidence.