July 22, 2025

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

Re: K251255
Trade/Device Name: LymphaTech Mobile 3D Measuring Tool
Regulation Number: 21 CFR 878.4160
Regulation Name: Surgical Camera And Accessories
Regulatory Class: Class I
Product Code: SFG
Dated: April 21, 2025
Received: April 23, 2025

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.

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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.07.22 12:31:24 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251255

Device Name
LymphaTech Mobile 3D Measuring Tool

Indications for Use *(Describe)*
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 3D Measuring Tool does not provide a diagnosis or therapy.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary: K251255

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: April 21, 2025

Subject Device: Trade Name: LymphaTech Mobile 3D Measuring Tool
Common Name: Camera, surgical, measurement
Classification Name: Surgical camera and accessories
Regulation: 21 CFR §878.4160
Regulatory Classification: Class 1
Product Code: SFG

Predicate Device: Scout (K131596)
Reference Device: decimal3D (K192554)

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 circumference of a part of the body. 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 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 is presented in the table below. The reference device (decimal3D) uses the same high-accuracy off-the-shelf long-wave infrared camera for a different intended use.

Table 1: Device Comparison

		Subject Device: LymphaTech Mobile 3D Measuring Tool	Predicate Device: WoundVision Scout	Comparison
Regulatory information	Manufacturer	LymphaTech	WoundVision LLC	N/A
	Product Code	SFG	FXN	A new product code
	Regulation Number	21 CFR 878.4160	21 CFR 878.4160	Identical.
	Device Classification Name	Camera, Surgical, Measurement	Tape, Camera, Surgical	Similar - Both for measurement
	Device Classification	1	1	Identical.
	Indication 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	The Scout is a combination digital camera and long-wave infrared camera. The digital camera is indicated for the use of capturing visual images to measure the diameter, surface area, and perimeter of a part of the body or two body surfaces. The long-wave infrared camera is indicated for the use of capturing thermal images to measure the thermal intensity data of a part of the body or two body surfaces. Both components of the Scout are non-contact with respect to the patient and provide an adjunctive tool to help a trained and qualified health care professional measure and record external wound and body surface data. Intended for qualified healthcare	Similar- Both devices measure the diameter, surface area, and perimeter of a part of the body. The subject device also measures volume. The predicate device measures temperature.

		Subject Device: LymphaTech Mobile 3D Measuring Tool	Predicate Device: WoundVision Scout	Comparison
		health care is provided by a qualified health care professional. The 3D Measuring Tool does not provide a diagnosis or therapy.	professionals who are trained in its use, the Scout is a non-invasive and non-radiating device. The Scout is to be used on a patient population that includes non-pregnant female or male patients 18 years of age or older. The Scout is intended to be used in hospital, acute and sub-acute care settings, long term care, surgery, health care practitioner facilities, outpatient, home healthcare, or in any environment where health care is provided by a qualified health care professional. The Scout does not provide a diagnosis or therapy.	
	Rx or OTC	Rx Only	Rx Only	Identical.
Principles of Operation		The subject device is software only.	The predicate device is a digital and thermal long-wave infrared camera that measures the desired body part.	Similar- Both devices record measurements.
Setting of Use		Clinical setting	Clinical setting	Identical.
User		Clinician	Clinician	Identical.
Patient Contact		Non-patient contacting	Non-patient contacting	Identical.
Measurements		Measure the diameter, surface area, volume and perimeter/circumference of a part of the body.	Measure the diameter, surface area, and perimeter of a part of the body or the distance	Similar- physical measurements. The subject device measures volume and does not

		Subject Device: LymphaTech Mobile 3D Measuring Tool	Predicate Device: WoundVision Scout	Comparison
			between two body surfaces. Measures temperature.	measure temperature.
Testing		Bench testing and clinical usability testing.	Bench testing and clinical usability testing.	Identical types of testing.
Software and Connectivity	Storage of data	Electronically records and stores source data .	Electronically records and stores source data.	Identical.
	Device connectivity	None required. Measurements and images remain on iPad.	Measurements and images can be updated to electronic medical records and are stored in the cloud. Connects to a portal and EMR.	Different- The predicate device requires connectivity to access data.
Hardware	Long-wave Infrared Camera	Measures infrared radiation on objects.	Measures infrared radiation on objects.	Identical.
	Computing Device	Off-the-Shelf iPad running iPad iOS 14 or higher.	N/A- No iPad or mobile device is required for the predicate device.	Different computing devices.

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
- Non-Clinical Bench Performance Testing including linear diameter and length accuracy testing, circumference and surface area testing, volume accuracy testing as compared to water displacement and perometry, and inter-operator variability assessment.

Conclusion

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