May 27, 2022

Delfin Technologies Ltd
% Patrick Danciu
President
F Care Systems USA (dba: Delfin USA LLC)
11098 Biscayne Blvd, Suite 301
Miami, Florida 33161

Re: K220557
Trade/Device Name: MoistureMeterD Compact, LymphScanner
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: OBH
Dated: January 17, 2022
Received: February 28, 2022

Dear Patrick Danciu:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Gema Gonzalez
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220557

Device Name

MoistureMeterD Compact and LymphScanner

Indications for Use *(Describe)*

MoistureMeterD Compact and LymphScanner is a device utilizing inter-arm ratios of tissue dielectric constant (TDC) that supports local assessment of tissue water differences between affected and contralateral non-affected arm tissues to aid in forming a clinical judgment of unilateral lymphedema in adult women. The device is not intended to make a diagnosis or predict arm lymphedema.

Enter description of indications for

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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Section 5 - 510(k) Summary

510(k) submitter's name:

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Contact Name: Patrick Danciu, President
Email: pdanciu@delfin-usa.com

Date Prepared: 27 May 2022

Device Identification:

Trade Name:	MoistureMeterD Compact and LymphScanner
Common name:	Moisturemeter
Classification Name:	Impedance Plethysmograph
Regulation Number:	21 CFR 870.2770
Product Code:	OBH
Panel:	Cardiovascular
Device Class:	Class II

Predicate device:

Company:	Delfin Technologies Ltd
Trade Name:	MoistureMeterD
510(k) Number:	K143310
Classification name:	Impedance Plethysmograph
Regulation number:	21 CFR 870.2770
Product code:	OBH
Classification panel:	Cardiovascular
Device class:	Class II

Delfin Technologies

General Description:

The MoistureMeterD Compact (MMDC) and the LymphScanner are identical differently labelled bioelectrical analyzers to measure localized tissue fluid content. High-frequency electromagnetic waves produced in the hand-held main unit are guided into integrated open-ended coaxial probe. When the probe is placed onto the skin, skin and upper subcutis is exposed to electromagnetic field. In skin and upper subcutis electromagnetic fields are interacting with tissue water molecules by rotation causing absorption of electromagnetic energy in tissue. The devices measure the amplitude and phase shift of the reflected electromagnetic wave and calculate tissue dielectric constant (TDC). Tissue dielectric constant (TDC) is an index of localized tissue water content. The measured TDC value can be converted into Percentage Water Content (PWC) value.

Indications for Use - MoistureMeterD Compact and LymphScanner:

MoistureMeterD Compact and LymphScanner is a device utilizing inter-aim ratios of tissue dielectric constant (TDC) that supports local assessment of tissue water differences between affected and contralateral non-affected aim tissues to aid in forming a clinical judgment of unilateral lymphedema in adult women. The device is not intended to make a diagnosis or predict arm lymphedema.

Technology:

The MoistureMeterD Compact and LymphScanner have the same technological characteristics as the predicate device MoistureMeterD, the essential difference being in the outlook of devices and probe construction. The MoistureMeterD Compact and LymphScanner are handheld battery-powered bioelectrical analyzers that contain a high-frequency electromagnetic wave generator and open-ended coaxial probe integrated into main unit. In the predicate bioelectrical analyzer MoistureMeterD applying the identical technological characteristics the probe is connected to main unit by coaxial cable.

Dimensions of the probe in the MoistureMeterD Compact and LymphScanner are identical to the M25 probe in the MoistureMeterD. Discussion related to substantial equivalence is thus focussed to compare performance characteristics between MoistureMeterD Compact or LymphScanner with the MoistureMeterD provided with M25 probe.

When the probes of the MoistureMeterD Compact, LymphScanner or the predicate device MoistureMeterD is placed onto the skin, the devices are guiding the electromagnetic waves into skin. After absorption of electromagnetic energy by tissue

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water molecules the amplitude and phase shift of the reflected wave are respectively measured by all devices. From this information the devices calculate tissue dielectric constant (TDC) in MoistureMeterD and from TDC converted value, Percentage Water Content (PWC) for the MoistureMeterD Compact and LymphScanner. Both TDC and PWC are directly proportional to localized tissue water content.

Substantial Equivalence:

The MoistureMeterD Compact and LymphScanner have the same indications for use statements with the predicate device MoistureMeterD provided with M25 probe. Substantial equivalence of the devices is based on clinical studies in healthy female volunteers, women waiting for surgery of breast cancer, women operated for breast cancer, women at risk for lymphedema or a diagnosis of lymphedema. From absolute measurement values of at risk or affected arm and contralateral non-affected arm the inter-arm TDC or PWC ratios are calculated by dividing the respective measurement values. The inter-arm ratio supports local assessment of tissue water tissue water differences between at risk or affected and contralateral non-affected arm.

Substantial equivalence between the MoistureMeterD Compact or LymphScanner and predicate MoistureMeterD provided with M25 probe was confirmed by determining the inter-arm TDC or PWC ratio in women with both instruments. Inter-arm TDC ratios were not statistically different with respect to device (MoistureMeterD Compact vs MMD provided with M25). Since the LymphScanner uses the same identical technology as the MoistureMeterD Compact, the same clinical performance data also concern the LymphScanner.

Clinical studies also confirmed that the inter-arm TDC or PWC ratio is a robust indicator to describe tissue water differences between at risk or affected and contralateral non-affected arm tissues since the inter-arm TDC or PWC ratio directly indicates percentage difference of tissue fluid contents of at risk or affected arm compared with contralateral non-affected arm.

Clinical results summarized that the MoistureMeterD Compact is safe to use in women without any adverse effects and meet the objective of substantial equivalency assessed using the robust inter-arm TDC or PWC ratios. Slight technological differences between the MoistureMeterD Compact or LymphScanner and predicate device MoistureMeterD do not raise any new issues on safety or effectiveness as discussed further within this submission.

Conclusion:

The MoistureMeterD Compact and LymphScanner described in this 510(k) notification are safe, equally effective and substantially equivalent to the predicate device MoistureMeterD provided with M25 probe.