DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 19, 2015

Delfin Technologies, Ltd.
% Theodore Sullivan
Counsel
Buchanan Ingersoll & Rooney, PC
1700 K Street NW Suite 300
Washington DC 20006

Re: K143310
Trade/Device Name: MoistureMeterD
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: OBH
Dated: October 16, 2015
Received: October 19, 2015

Dear Theodore Sullivan,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K143310

Device Name: MoistureMeterD

Indications For Use:

Delfin MoistureMeterD 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 women. The device is not intended to make diagnosis or predict arm lymphedema.

Prescription Use ____x___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitters Name and Address:
Delfin Technologies Ltd
Microkatu 1
P.O Box 1199
FI-70211 Kuopio FINLAND

Contact Name: Jouni Nuutinen
Date Prepared: 4/18/2012

Device Identification:
Trade Name: MoistureMeterD
Classification Name: Impedance Plethysmograph
Regulation Number: 21 CFR 870.2770
Product Code: OBH
Panel: Cardiovascular
Device Class: Class II

Predicate device:
Company: ImpediMed Limited
Trade Name: L-Dex U400 BIS Extra Cellular Fluid Analysis
510(k) Number: K080825
Classification name: Impedance Plethysmograph
Regulation number: 870.2770
Product code: OBH
Classification panel: Cardiovascular
Device class: Class II

General Description:

The Delfin MoistureMeterD is a high-frequency bioelectrical analyzer used to detect tissue fluid. The device accurately measures voltage, current and the phase shift of the reflected current of the attenuated electric field and calculate capacitance and, moreover the tissue dielectric constant (TDC). The tissue dielectric constant (TDC) supports the measurement of local tissue fluid.

Intended Use / Indications for Use:

Delfin MoistureMeterD 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 women. The device is not intended to make diagnosis or predict arm lymphedema.

Technology:

MoistureMeterD is a bioelectrical analyzer that contains two-electrode systems. The device accurately measures voltage, current and the phase shift of the reflected current of the attenuated electric field and calculate capacitance, and moreover the tissue dielectric constant (TDC). The TDC supports the measurement of local tissue fluid. The device operates at a single frequency at 265 +/-20 MHz. At high radiofrequency both extra and intra cellular fluid volume is reached. The MoistureMeterD is battery operated device.

Substantial Equivalence:

MoistureMeterD product has the same intended use as a previous device and similar indications. MoistureMeterD provides information on tissue fluid volume and are used by or under supervision of physicians or other professionals to assist in forming a clinical judgement. The slight technological differences do not raise any new issues on safety or effectiveness as discussed further within this submission.

Conclusion:

For all of the foregoing reasons, Delfin Technology Ltd believes that the MoistureMeterD described in this 510(k) notification is substantially equivalent to the predicate device and may be safely marketed in the United States.