DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 8, 2015

Podimetrics, Inc.
Jonathan Bloom, MD
CEO and Co-Founder
231 R Holland Street
Somerville, Massachusetts 02144

Re: K150557
Trade/Device Name: Podimetrics Remote Temperature Monitoring System™
Regulation Number: 21 CFR 890.5050
Regulation Name: Daily Activity Assist Device
Regulatory Class: I
Product Code: OIZ
Dated: September 1, 2015
Received: September 2, 2015

Dear Dr. Bloom:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Tina Kiang -S

for Erin I. Keith, MS
Director
Division of Dental, Anesthesiology, General Hospital,
Respiratory, and Infection Control Devices
Office of Device Evaluation
Center for Devices and Radiological Devices

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150557

Device Name
Podimetrics Remote Temperature Monitoring System

Indications for Use *(Describe)*

The Podimetrics Remote Temperature Monitoring System™ (RTM System™) is intended to be used by a patient in conjunction with a healthcare professional or caretaker for periodic evaluation of the temperature over the soles of the feet for signs of inflammation. It will provide information indicating when the patient and healthcare provider should communicate for further evaluation and treatment regarding any persistent localized inflammation observed on the feet via the electronic sensing system and remote visualization of its data. The Podimetrics RTM System™ is intended to be used under the direction of a healthcare professional as an adjunct to, and not in replacement of, self-examination and periodic foot care and examination conducted by a healthcare professional and does not diagnose any specific disease state.

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.

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008_Summary

PODIMETRICS

K150557

510(k) Summary
for the Podimetrics Remote Temperature Monitoring System™

8.1 Submitter/510(k) Holder

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Date Prepared: February 23, 2015

8.2 Device Name

Trade Name: Podimetrics Remote Temperature Monitoring System™
Common Name: Foot Temperature Monitor
Classification Name: Daily Activity Assist Device, (Product Code OIZ, 21 CFR 890.5050)
Device Classification: Class I

8.3 Predicate Device

Visual Footcare Technologies TempStat™ (K080816, Product Code OIZ)

8.4 Indications for Use

The Podimetrics Remote Temperature Monitoring System™ (RTM System™) is intended to be used by a patient in conjunction with a healthcare professional or caretaker for periodic evaluation of the temperature over the soles of the feet for signs of inflammation. It will provide information indicating when the patient and

healthcare provider should communicate for further evaluation and treatment regarding any persistent localized inflammation observed on the feet via the electronic sensing system and remote visualization of its data. The Podimetrics RTM System™ is intended to be used under the direction of a healthcare professional as an adjunct to, and not in replacement of, self-examination and periodic foot care and examination conducted by a healthcare professional and does not diagnose any specific disease state.

8.5 Device Description

The Podimetrics RTM System™ is designed to help a patient and healthcare professional periodically evaluate the temperature over the soles of the feet for signs of inflammation. This evaluation may be helpful for determining when the patient and healthcare provider should communicate for physical examinations or care in addition to normally scheduled visits.

The system is comprised of the Podimetrics Mat and the Thermogram Explorer™ internet application. The Podimetrics Mat is about the same size and shape as a floor mat and placed on the floor of the patient's home. The patient stands on the mat once per day for about 20 seconds to collect a thermal scan of the soles of the feet. The thermal scan is recorded electronically via 2-dimensional array of temperature-sensitive resistors covering the top surface of the mat and the data is transmitted by an internal cellular modem to a remote server via cellular network.

The thermal scan data is processed and stored on the remote server and is displayed in Thermogram Explorer™, an internet application. The patient and healthcare professional can use Thermogram Explorer™ to access the thermograms and evaluate them for signs of inflammation. If any signs are observed, the patient can see the healthcare professional for a physical examination.

8.6 Technological Characteristics and Substantial Equivalence

The Podimetrics RTM System is substantially equivalent to the Visual Footcare Technologies, LLC TempStat™. Both devices include a sensor pad upon which the feet are placed to measure the temperature across the plantar surface of the feet.

The TempStat™ uses liquid crystals embedded in a polycarbonate plastic which change color corresponding to the skin temperature they are in contact with. The Podimetrics RTM System™ uses electronic temperature-sensitive resistors encased in a polyurethane elastomer which record the temperature applied and display it on a computer. Although the technological method differs, both devices generate a 2-dimensional heat map, or thermogram, of the feet which can be used to evaluate for signs of inflammation in the same manner. Both devices produce thermograms that are evaluated by the patient, and the Podimetrics RTM System™ can additionally be accessed by the healthcare provider for remote evaluation. This may lead to more

frequent communication and physical examination by the healthcare professional compared to the standard of care.

The differences in the intended use between the Podimetrics RTM System™ and the TempStat™ are minor and do not affect the device's intended use.

The following table contains a summary of the descriptive and technological characteristics of the Podimetrics RTM System™ compared to the predicate device.

Characteristic	**TempStat™ (K080816)**	**Podimetrics RTM System™**	**Discussion of equivalency**
Manufacturer	Visual Footcare Technologies	Podimetrics	
Product Code	OIZ	OIZ	Same
CFR	890.5050	890.5050	Same
Intended Use	Foot examination tool used for potential inflammatory changes	Foot examination tool used for potential inflammatory changes	Same

Characteristic	TempStat™ (K080816)	Podimetrics RTM System™	Discussion of equivalency
Indications for use	TempStat is a daily activity assist device that is intended to assist a patient to visualize the image and condition of the soles of their feet in connection with a daily self-examination for signs of inflammation on the sole of the foot. TempStat will assist the patient in determining when they should contact their healthcare provider for further diagnosis and treatment regarding any skin changes seen by a mirror and/or highlighted by the liquid crystal foot pads. TempStat is intended to be used as an adjunct to, and not in replacement of, periodic foot care and examinations conducted by a health care professional and used under the direction of a health care professional and does not diagnose any specific disease state.	The Podimetrics Remote Temperature Monitoring (RTM) System™ is intended to be used by a patient for periodic evaluation of the temperature over the soles of the feet for signs of inflammation in conjunction with a healthcare professional or caretaker. It will assist in determining when the patient and healthcare provider should communicate for further diagnosis and treatment regarding any persistent localized inflammation observed on their feet via the electronic sensing system and remote visualization of its data. The Podimetrics RTM System is intended to be used under the direction of a healthcare professional as an adjunct to, and not in replacement of, self-examination and periodic foot care and examination conducted by a healthcare professional and does not diagnose any specific disease state.	Similar. Whereas the predicate device displays the thermal data qualitatively in a color-map on the device, the Podimetrics RTM System measures temperature electronically and displays the same type of data quantitatively for evaluation by the patient and healthcare provider through a web application.
Prescription Use	The TempStat™ is for prescription only.	The Podimetrics RTM System™ is for prescription only.	Same
Target population	Marketed for diabetics, especially those with neuropathy and risk for foot ulcers or other inflammatory conditions.	Marketed for diabetics, especially those with neuropathy and risk for foot ulcers or other inflammatory conditions.	Same

Characteristic	TempStat™ (K080816)	Podimetrics RTM System™	Discussion of equivalency
Anatomical site	The plantar aspect of the feet.	The plantar aspect of the feet.	Same
Where used	The patient's home.	The patient's home.	Same
Performance	Liquid crystal pads are accurate to within 1°F with respect to color changes.	Electronic sensors are accurate to within 1°F.	Same
Data format	Provides a color-coded thermogram on the surface of the device.	Provides a color-coded and quantitative thermogram with actual temperature in the web application.	Both devices generate and display a color-coded thermogram of the feet. The Podimetrics RTM System™ additionally displays the temperature quantitatively in Thermogram Explorer™.
Energy used and/or delivered	No energy is used or delivered.	The Podimetrics Mat is powered by a rechargeable battery but does not deliver any energy.	Neither device delivers any energy to the patient.
Human Factors	The user places their feet on the TempStat sensing pads for 60 seconds while sitting.	The user stands on the Podimetrics Mat for 20 seconds.	Both devices are placed on the floor and require the user to place their feet on the top surface for a short measurement.
Materials and Biocompatibility	Foot contacting material: Liquid crystals encased within polycarbonate plastic.	Foot contacting material: Polyurethane film with silver ion additive	Although the specific materials differ between the Podimetrics and predicated device, the patient-contacting material of the Podimetrics product has been tested in accordance with ISO 10993 parts 5, 10, and 11.

Characteristic	TempStat™ (K080816)	Podimetrics RTM System™	Discussion of equivalency
Compatibility with the environment and other devices	TempStat™ includes no electronics or chemicals so there are no compatibility concerns.	The Podimetrics Mat includes electronics to perform thermal scans and which use RF wireless technology to transmit the data.	The Podimetrics Mat has been tested for EMC in accordance with IEC 60601-1-2 and is subject to FCC certification before marketing.
Electrical Safety	The TempStat™ includes no electronics.	The Podimetrics Mat includes electronics for temperature sensing, user interface, data storage, and data transmission.	The Podimetrics Mat has been tested for electrical safety in accordance with IEC 60601-1 and IEC 60601-1-11.
Software	The TempStat™ includes no software.	The Podimetrics RTM System™ uses software to generate, store, process, and visualize thermometric data.	The Podimetrics RTM System™ includes software which adheres to "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" issued on January 11, 2002.

8.7 Performance Characteristics of the Podimetrics RTM System™

The Podimetrics RTM System™ underwent a series of bench testing to demonstrate it is as safe and effective as the predicate for its intended use. Testing included:

- Accuracy: The Podimetrics RTM System™ is accurate within 1°F over the range 59 to 104°F, with a precision of 0.5°F and a temperature resolution of 0.2°F.

- Scan time: Each thermal scan requires approximately 20 seconds to complete using the Podimetrics Mat as demonstrated through laboratory bench testing and the human factors testing performed.

- Battery life: The Podimetrics Mat is cordless, has a battery life of greater than one month of daily use.

- Battery safety: The rechargeable battery was tested for protection against overheating, over-discharging, and over-charging and met test requirements.

- Service life: The service life of the Podimetrics Mat is greater than 2 years of daily use as demonstrated through cyclic loading tests, battery charge/discharge cycles, and cleaning tests.

- Electrical safety: The Podimetrics Mat has been tested for electromagnetic compatibility and electrical safety in the home healthcare environment in accordance with IEC 60601-1 (3rd edition), 60601-1-2 (3rd edition), and 60601-1-11 (1st edition). The device met all requirements of the testing.

- Wireless data transmission: The Podimetrics RTM System™ transmits data wirelessly securely and without loss of data. In the event of an inaccessible cellular network, the data is saved locally and transmitted upon reconnection.

- Human Factors: Podimetrics has conducted a 14-day in-home human factors study to assess the ability of users to use the Podimetrics Mat at home. No patients reported any problems setting up the device, taking and transmitting thermal scans, or charging the batteries. No issues were identified. Podimetrics has also conducted a human factors study for the Thermogram Explorer web application to verify users can display a thermogram for a particular patient and compare temperatures between two locations on the feet.

- Biocompatibility: The patient-contacting material of the Podimetrics Mat has been tested for biocompatibility for the type of contact and duration of contact. The testing demonstrated that the patient contacting material met the individual test requirements and is considered biocompatible for the product's intended use.

- Floor safety: The top and bottom surface of the Podimetrics Mat were tested for non-slip properties. The product met the test criterion and is not considered a trip hazard.

- Shipping: The Podimetrics Mat packaging was tested to ensure the device maintains performance after shipping. The device functioned as intended post ship testing.

All testing performed demonstrates that the Podimetrics RTM System™ is as safe and effective as the predicate as an aid in detecting inflammation on the soles of a patient's foot.

8.8 Conclusion

Podimetrics believes that, based on the descriptive information and testing provided in this submission, the Podimetrics RTM System™ is substantially equivalent to its predicate device.