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

January 14, 2015

Medical Monofilament Manufacturing
% Susan Hamann
Consultant
Alvamed
21 Phillip Ave
Burlington, Massachusetts 01803

Re: K143068
Trade/Device Name: Fit2Walk Monofilament Sensory Screening Tool
Regulation Number: 21 CFR 882.1500
Regulation Name: Esthesiometer
Regulatory Class: Class I
Product Code: GXB
Dated: October 22, 2014
Received: October 31, 2014

Dear Ms. Hamann,

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" (21 CFR 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,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143068

Device Name
Fit2Walk Monofilament Sensory Screening Tool

Indications for Use *(Describe)*
The Fit2Walk Monofilament Sensory Screening Tool is intended to be used to determine whether a person with diabetes has the presence of an adequate level of protective sensation in their feet as indicated by having enough tactile sensitivity in order to perceive 10 grams of force against the skin of their feet.

It is indicated for use by adult Diabetic patients on a periodic basis to evaluate changes in sensory perception in the feet due to Diabetic peripheral sensory neuropathy. This device is not to be considered a replacement for routine sensory evaluation by a health care provider.

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."

M E D I C A L M O N O F I L A M E N T M A N U F A C T U R I N G

121-2 CAMELOT DRIVE, PLYMOUTH, MA, USA 02360

P: 508.746.7877 F: 508.746.540

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

January 6, 2015

Name of Submitter:

Medical Monofilament Manufacturing
121 Camelot Drive
Plymouth, MA 02360

Phone: 508-746-7877
Fax: 508-746-5409

Corresponding Official:
Michelle Hardiman
CEO

Device Proprietary Name:
Fit2Walk Monofilament Sensory Screening Tool

Common Name:
Sensory Screening Tool

Classification Name:
Esthesiometer (21 CFR 882.1500, Product Code GXB)

Substantial Equivalence:
The Fit2Walk Monofilament Sensory Screening Tool is substantially equivalent to the following device that is currently legally marketed: Medical Monofilament Sensory Testing Filament.

Device Description:

Monofilaments are devices that contain a small strand of filament attached to a handle. When placed upon the skin, they apply a certain amount of pressure before the filament bends or buckles. The point at which the filament bends or buckles is rated in grams of force. Monofilaments are primarily used to check for a certain level of sensation present in the skin in different parts of the body. The ten gram monofilament has been widely accepted by the medical community to evaluate the level of sensation in the skin of the feet for evaluating severe diabetic peripheral sensory neuropathy or LOPS (loss of protective sensation) of the feet.

Intended Use/Indications for Use:
The Fit2Walk Monofilament Sensory Screening Tool is intended to be used to determine whether a person with diabetes has the presence of an adequate level of protective sensation in their feet as indicated by having enough tactile sensitivity in order to perceive 10 grams of force against the skin of their feet.

It is indicated for use by adult Diabetic patients on a periodic basis to evaluate changes in sensory perception in the feet due to Diabetic peripheral sensory neuropathy. This device is not to be considered a replacement for routine sensory evaluation by a health care provider.

Comparison of Features for the Fit2Walk Monofilament Sensory Screening Tool and the Medical Monofilament Sensory Testing Monofilament.

Feature	Fit2Walk Monofilament Sensory Screening Tool	Medical Monofilament Sensory Testing Filament.
Intended Use	The Fit2Walk Monofilament Sensory Screening Tool is intended to be used to determine whether a person with diabetes has the presence of an adequate level of protective sensation in their feet as indicated by having enough tactile sensitivity in order to perceive 10 grams of force against the skin of their feet. It is indicated for use by adult Diabetic patients on a periodic	The Medical Monofilament Sensory Testing Filament is intended to be used by medical personnel to determine whether a person with diabetes has the presence of an adequate level of protective sensation in their feet as indicated by having enough tactile sensitivity in order to perceive 10 grams of force against the skin of their feet.

	basis to evaluate changes in sensory perception in the feet due to Diabetic peripheral sensory neuropathy. This device is not to be considered a replacement for routine sensory evaluation by a health care provider.	
Filament material	Polyester	Polyester
Semmes-Weinstein number (firmness)	5.07	5.07
Force Range	10 gram (Range 8.5-11.5)	10 gram (Range 8.5-11.5)
Availability	The Fit2Walk kit will initially be available online, but may also be available at retail stores in the future.	Available to medical practitioners online at www.medicalmonofilament.com

Performance Data:
Included in this submission is a report from Diabetes Care, Vol. 21, Number 1, January 1998, "Evaluation of a Self-Administered Sensory Testing Tool to Identify Patients at Risk of Diabetes-Related Foot Problems" written by James A Birke and Robert Rolfsen. The paper describes a study concerning the use of a self-administered sensory testing tool designed to identify individuals at risk for diabetes-related foot problems and determine the inter-rater reliability between patient and provider sensory evaluations.

Conclusion:
The Fit2Walk Monofilament Sensory Screening Tool is substantially equivalent to the Medical Monofilament Sensory Testing Filament.