DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 9, 2017

Hoggan Scientific, LLC
Spencer Walker
Director Regulatory Affairs
3653 West 1987 South Bld. # 7
Salt Lake City, Utah 84104

Re: K162412
Trade/Device Name: MicroFET2™ System
Regulation Number: 21 CFR 888.1240
Regulation Name: AC-Powered Dynamometer
Regulatory Class: Class II
Product Code: LBB
Dated: February 17, 2017
Received: February 27, 2017

Dear Mr. Walker:

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,

Michael J. Hoffmann -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)*
K162412

Device Name
Hoggan Scientific® microFET2™

Indications for Use *(Describe)*
The microFET2™ System is a dynamometer device for performing muscle tests to quantitatively measure muscle weakness caused by injury or for sports medicine applications, as well as measure general muscle strength. The device is used to record and convey an individual's ability to resist force for a specific muscle or muscle group being tested.

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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510(k) Summary

Submitter: Hoggan Scientific, LLC

Contact Person: Spencer Walker, MSc - Director Regulatory Affairs
3653 West 1987 South Bld. # 7
Salt Lake City, UT 84104
(801) 581-5080

Date Prepared: August 23, 2016

Trade Name: microFET2™

Classification Name: Dynamometer
21 CFR §888.1240, Product Code LBB, Class II

Predicate Device(s):

- K042889– Ametek, Inc., Dynamometer, Model Chatillon FCE and MSC series;

Device Description:

The microFET2™ is an ergonomically designed hand-held, battery operated, digital muscle tester. Which is an accurate, portable Force Evaluation Testing (FET) dynamometer, designed specifically for taking objective, reliable, and quantifiable muscle testing measurements, and is used to record a person's ability to resist force for a specific muscle or muscle group being tested.

The device's ergonomic design allows for its use ambidextrously, depending on stabilization requirements, by being held in either hand using an elastic strap for convenience and comfort. The size and weight of the device allows the examiner/tester to use the same procedures and methods of muscle testing techniques without causing injury to the clinician or patient.

Indications for Use:

The microFET2™ system is a dynamometer device for performing muscle tests to quantitatively measure muscle weakness caused by injury, or for sports medicine applications, as well as measure general muscle strength. The device is used to record and convey an individual's ability to resist force for a specific muscle or muscle group being tested.

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Comparative Analysis:

The microFET2™ is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The microFET2™ system has been fully assessed within the Hoggan Scientific Risk Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria to confirm safety and effectiveness.

Technology Comparison of microFET2™ with Predicate Device:		
Device Component	**Subject Device – K162412**	**Predicate – K042889 – Ametek (Chatillon FCE & MSC)**
Device Name	microFET2™	MSC Series Digital Muscle Strength Comparator, Chatillon/Ametek
Intended Use	The microFET2™ is a dynamometer diagnostic device used for quantitatively evaluating muscle strength	The Chatillon FCE and MSC series dynamometers are diagnostic devices used for quantitatively evaluating muscle strength
Indications for use	The microFET2™ system is a dynamometer device for performing muscle tests to quantitatively measure muscle weakness caused by injury or for sports medicine applications, as well as measure general muscle strength. The device is used to record and convey an individual's ability to resist force for a specific muscle or muscle group being tested.	The intended use of the Chatillon FCE and MSC series dynamometers is for performing manual muscle testing to measure muscle strength. The target population for this product is individuals recovering from physical injury or for sports medicine applications
Classification	AC-Powered Dynamometer 21CFR 888.1240 Product Code: LBB Class II	AC-Powered Dynamometer 21CFR 888.1240 Product Code: LBB Class II
Prescription (Rx Only)	Yes	Yes
Anatomical site	Head, Neck, Shoulders, Arms, Elbows, Wrists, Hands, Fingers, Hips, Legs, Knees, Ankles, Feet, Toes	Head, Neck, Shoulders, Arms, Elbows, Wrists, Hands, Fingers, Hips, Legs, Knees, Ankles, Feet, Toes
Measurement	0.8 lbf Minimum - 300 lbf Maximum With 0.1 lbf resolution	100 lbf Maximum with 0.01 lbf resolution 200 lbf Maximum with 0.02 lbf resolution 500 lbf Maximum with 0.05 lbf resolution
Unit of Measurement	Displays force as lbf, Kgf, N	Displays force as lbf, Kgf, N, gf, ozf
Power Supply	Battery Powered – May not to be operated while attached to charger.	Battery Powered - May be operated while attached to a charger

Battery	3.7 V Lithium-Ion Battery 90 hours continuous use (non-wireless mode) 6 hours continuous use (wireless mode)	4.8V Nickel Metal Hydride Battery 30 hours continuous use
Human factors	• Handheld • <1 lb. • Two small LCD displays • Two switches for user interaction • Wireless RF • Bluetooth data transfer	• Handheld • 1.5 lb. • Single large LCD display • Navigation Keys for user interaction with menu
Fundamental Scientific Technology	Resistance based strain gauge (Load Cell) with microprocessor to convert analog signal to digital, calibrated data	Resistance based strain gauge (Load Cell) with microprocessor to convert analog signal to digital, calibrated data
Sterilization	None	None
Radiation safety:	IEC 60417-5140 (Non-ionizing Radiation) IEC 61000-4-8 Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-3 RF Radiated Fields Immunity IEC 61000-4-2 Electrostatic Discharge CISPR 11 Group1 Class B	BS EN 61010-1:2001 Safety Requirement for Electrical Equipment BS EN 50081-1:1992 EMC Generic Emissions Standard BS EN 50082-1:1992 EMC Generic Immunity Standard
Applied Part Class (per IEC 60601-2-18; (2009))	Class II ME Type B	Class II ME Type B

Functional/Safety Testing:

The following functional tests were performed. All data met pre-determined acceptance criteria.

- **Biocompatibility** – The microFET2™ materials are the same as those from the Hoggan reference device per K860226. A new warning was added to the Instructions for Use manual advising the user to use the foam portion of the device over clothing.

- **Electrical Safety and Electromagnetic Compatibility (EMC)** – The electrical safety and EMC series of test demonstrates the safety and compatibility of the electrical and EMC characteristics of the microFET2™. The microFET2™ was tested to the requirements of the following industry standards:
  - IEC 60601-1 Medical Device Electrical Safety (2012)
  - IEC 60601-1-2 Medical Device (2014)
  - CISPR 11 Emissions Class B (2009), A1(2010)
  - FCC Part 15B - Radiated Emissions Conducted Emissions

- **Software** – The microFET2™ system uses firmware to control the handheld device:
    - Battery usage, load cell force conversion to LCD display screens and Bluetooth wireless capabilities

  The optional Clinical Software may be used to wirelessly record patient testing results and record keeping.

  The optional FET Data Collection Software may be used to plot the data on a computer monitor in real time.

  The microFET2™ firmware/software level of concern have been determined to be minor, and are deemed to not result in harm to the patient or misdiagnosis of the patient condition when the device is used by a medical professional.

Conclusion:

The microFET2™ is substantially equivalent to the cited predicate device. Additionally, the microFET2™ met all acceptance criteria to confirm safety and effectiveness.