November 1, 2019

TensCare Ltd.
Andrew Brown
Quality Manager
9 Blenheim Road, Longmead Business Park
Epsom, Surrey, KT19 9BE Gb
UNITED KINGDOM

Re: K191312
Trade/Device Name: Perfect PFE
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: August 5, 2019
Received: August 13, 2019

Dear Andrew Brown:

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,

for
Angel Soler-Garcia, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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)*
K191312

Device Name
Perfect PFE

Indications for Use *(Describe)*
Perfect PFE is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

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."

510(k) Summary

Date of Submission prepared: November 1st 2019

I Submitter

Tenscare Ltd
Address: 9 Blenheim Road, Longmead Business Park, Epsom, Surrey, KT19 9BE, United Kingdom
Tel : +44(0)1372 723 434
Fax : +44(0)1372 745 434
E-Mail : andrew@tenscare.co.uk
FDA Establishment Registration No: 3003446042
Contact person: Andrew Brown

Address of the manufacturing facility:

EasyMed Instruments Co Ltd
3/F, 5F/6F, Block A, Gupo Gongmao Building,
Fengxin Road, Fengxiang Industrial District,
Daliang, 528300 Shunde, Foshan, Guangdong,
China

FDA Establishment Registration No: 3004049909

Address of American Representative:

Stephanie McNeil
5828 Lakeshore Road
Fort Gratiot
Michigan 48059
USA
Phone: 001 800 308 7390
Email: compliance@tenscare.com

II Submitted Device:

Trade name: Perfect PFE
Common name: Pelvic Floor Stimulator
Classification number: 21 CFR 876.5320
Classification name: Nonimplanted electrical continence device
Product Code: KPI (Stimulator, electrical, non-implantable, for incontinence)
Classification Panel: Gastroenterology and Urology
Regulatory Class: Class II

III Predicate Device:

Predicate Device (1): Primary Predicate
Trade/Device Name: Tenscare KegelFit
Manufacturer: TensCare Ltd
510(k) Number: K142506
Product Code: KPI
Type of Use: Over-The-Counter Use (OTC Use)
Regulatory Class: Class II

Predicate Device (2): Secondary Predicate
Trade/Device Name: Yarlap
Manufacturer: International Trade Group, Inc.
510(k) Number: K141643
Product Code: KPI
Type of Use: Prescription Use and Over-The-Counter Use (OTC Use)
Regulatory Class: Class II

IV Device Description:

The Perfect PFE is a hand-held, home-use device designed to treat stress, urge and mixed urinary continence in women and maintain urinary continence in women. The device is supplied with a reusable (single-patient use) vaginal, dual-electrode, stimulation probe. The probe connects to the control unit by cable and plug and is inserted into the vagina by the end user. The probe has a recommended usage duration of 6 months.

The device is battery powered, single channel, home use neuromuscular stimulation. Electrical stimulation is delivered via stainless steel electrodes on the probe to induce a contraction of the pelvic floor muscles. Muscle stimulation is used to train and strengthen the pelvic floor muscles in a controlled manner. Muscle stimulation is used to improve the ability of muscles to hold a contraction for an extended period of time and is a treatment for urinary incontinence. During a session, stimulation is delivered to specific muscles to encourage their contraction. This contraction strengthens the muscles and also helps the end user recognize which muscles to activate during self-directed contractions. The level of electrical stimulation is easily controlled by the end user using manual, push-button controls.

The unit is intended for home use by the patient. It has four preset treatment programs, a preset treatment timer, a compliance monitor, and open circuit detectors.

Accessories:
Lead Wire (L-CPT)
Liberty Loop vaginal probe (X-VPL)

V Indications for Use of the device:

The Perfect PFE is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women and to maintain urinary continence in women.

The Perfect PFE is intended for OTC use.

VI Equivalence Comparison to the Predicate Devices:

Electrical muscle stimulation is the technological principle for both the Perfect PFE and the predicate devices KegelFit (K142506) and Yarlap (K141643). It is based on the use of the electrical muscle stimulator to strengthen the pelvic floor muscles.

The intended use and indications for use of the Perfect PFE are the same as those of the predicate devices.

The technical characteristics of Perfect PFE are similar to those of the predicate devices in design, intended use and function. The predicate device KegelFit (K142506), Yarlap (K141643) and the Perfect PFE are devices apply an electrical current via probe to a patient's pelvic floor muscles.

The stimulation parameters of Perfect PFE are similar to those of predicate devices KegelFit (K142506) and Yarlap (K141643). Perfect PFE has 4 programs, the parameters of the Stress and Tone programs are the same as those of predicate device KegelFit (K142506). The Urge program of Perfect PFE has employed similar parameters to the predicate device Yarlap (K141643). The parameters of the Mixed program of Perfect PFE is similar to both KegelFit (K142506) and Yarlap (K141643).

Table 1 below summarizes the shared and unique technological elements between the Perfect PFE, KegelFit (K142506), and Yarlap (K141643) devices. The technology, engineering, and performance for Perfect PFE are substantially equivalent to the predicate devices.

From the view of safety and effectiveness, the Perfect PFE uses preset programs that are substantially equivalently to the predicate devices. The output characteristics of Perfect PFE are similar to those of predicate device KegelFit (K142506), and Yarlap (K141643), see Table 1. The Perfect PFE is designed to comply with relevant safety applicable recognized consensus standards; the output energy is controlled well within the safety and effectiveness ranges specified by relevant FDA guidance. Detailed and strictly controlled testing has been carried out. The maximum power density of Perfect PFE and predicate device KegelFit (K142506), and Yarlap (K141643) are less than 0.25 watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns. Furthermore, the test results, risk analysis, and FMEA analysis show that the potential hazards of the Perfect PFE have been adequately mitigated.

As such:
1. the Perfect PFE has similar technological characteristics and intended uses as the predicate KegelFit (K142506) and Yarlap (K141643); and
2. the information submitted to the FDA for the Perfect PFE does not raise different questions about safety or effectiveness and performance testing demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as a legally marketed device.

Table 1 Substantial Equivalence Comparison Table

Attribute	Subject Device	Predicate Device (1)	Predicate Device (2)	Comparison
Product Name	Perfect PFE	KegelFit	Yarlap	
510(K) number	(to be assigned)	K142506	K141643	
Product Code	KPI	KPI	KPI	Substantially equivalent
Regulation No.	21 CFR 876.5320	21 CFR 876.5320	21 CFR 876.5320	Substantially equivalent
Indications for Use	Perfect PFE is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.	KegelFit is a non-implanted muscle stimulator designed to treat female stress urinary incontinence. It applies stimulation to the pelvic floor muscles to improve strength and support. The KegelFit is intended for OTC sale.	The device is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.	Substantially equivalent
Prescriptive or OTC	OTC	OTC	Rx and OTC	Substantially equivalent
Number of output modes	4	2	6	Substantially equivalent
Number of output channels	1	1	2	Substantially equivalent
Frequency (Hz)	Stress: 50Hz Tone: 35Hz Mixed: 10Hz/50 Hz Urge: 10Hz	Stress: 50Hz Tone: 35Hz	Stress: 12Hz / 35Hz Urge: 10Hz / 12Hz Mixed: 12Hz / 20Hz	Substantially equivalent

Attribute	Subject Device	Predicate Device (1)	Predicate Device (2)	Comparison
Pulse Width (µs)	Stress: 300µs Tone: 250µs Mixed: 200µs / 300µs Urge: 200µs	Stress: 300µs Tone: 250µs	Stress: 200µs / 250µs Urge: 200µs Mixed: 200µs / 250µs	Substantially equivalent
Maximum Output Voltage (V)	45V @ 500Ω	45V @ 500Ω	40V @ 500Ω	Substantially equivalent
Maximum Output Current (A)	0.09A @ 500Ω	0.09A @ 500Ω	0.08A @ 500Ω	Substantially equivalent
Maximum Phase Charge (µC)	24.29 @ 500Ω	23.88 @ 500Ω	20.85 @ 500Ω	Substantially equivalent
Maximum Current Density, (mA/cm^2)	21.2 @ 500Ω (Area=4.24cm^2)	10.5 @ 500Ω (Area=8.58cm^2)	12.5@ 500Ω (Area=6.4cm^2)	Substantially equivalent
Maximum Power Density, (W/cm^2)	0.0116 @ 500Ω (Area=4.24cm^2)	0.00584 @ 500Ω (Area=8.58cm^2)	0.0035 @ 500Ω (Area=6.4cm^2)	Substantially equivalent
Power Source	2 Alkaline AA 1.5V Batteries	2 Alkaline AA 1.5V Batteries	9V Alkaline Batteries	Substantially equivalent
Electrode lead wires and patient cable compliance with 21 CFR 898	Yes	Yes	Yes	Substantially equivalent

VII Vaginal Electrodes Substantial Equivalence and Safety:

The vaginal probe used with the subject device (i.e., the Liberty Loop vaginal probe) is similar in size, materials, and electrode position to the Liberty vaginal probe used with the KegelFit predicate device (K142506). Additionally, both probes are reusable, for single-patient use only. The main difference is that the subject Liberty Loop vaginal probe has an oval loop shape that can be squeezed during Kegel exercises, while the predicate Liberty vaginal probe is solid (not compressible). Despite this difference, the subject and predicate vaginal probes are substantially equivalent with respect to treating urinary incontinence.

VIII Performance Tests:

FDA recognition No.	Standard Title
19-4	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
19-8	IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
19-14	IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
17-16	IEC 60601-2-10 Edition 2.1 2016-04 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
5-40	ISO 14971: Second Edition 2007-03-01 Medical devices-Application of Risk Management To Medical Devices.
5-89	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
2-220	ANSI AAMI ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process Three biocompatibility tests conducted:

- Cytotoxicity (per ISO 10993-5)
- Sensitization (per ISO 10993-10)
- Irritation (per ISO 10993-10)

IX Usability Study:

Based on the similarity of the Perfect PFE to the predicates with respect to design, indications for use, and labeling materials, usability testing was determined not to be necessary for this 510(k) submission.

X Conclusion:

- The Perfect PFE has similar technological characteristics and intended uses as the predicate KegelFit (K142506) and Yarlap (K141643); and

- The labelling of the Perfect PFE is concordant with the predicate devices and FDA requirements; and

- The information and performance testing submitted to the FDA for the Perfect PFE does not raise different questions about safety or effectiveness and demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as a legally marketed device.

Therefore, the Perfect PFE is substantially equivalent to the predicate devices.