October 20, 2023

TensCare Ltd
Saskia Eldridge-Hinmers
Regulatory Affairs Associate
9 Blenheim Road
Epsom, Surrey KT19 9BE
United Kingdom

Re: K230983
Trade/Device Name: Unicare (K-UNICARE-USA)
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: April 12, 2023
Received: September 20, 2023

Dear Saskia Eldridge-Hinmers:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230983

Device Name
Unicare (K-UNICARE-USA)

Indications for Use *(Describe)*
Unicare 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.

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510 (k) Summary

1. Submitter Information

510 (k) submitter:	TensCare Ltd.
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Applicant Contact Person:	Saskia Eldridge-Hinmers Regulatory Affairs Associate Phone: +44(0)7879424785 Email : Saskia.Eldridge-Hinmers@tenscare.co.uk
American Representative:	Mr. Scott A Bednar QA/RA Consulting Group, Inc. 3335 Tuscarawas Road, Beaver Pennsylvania 15009 Phone: 412-418-8066 Email : sbednar@qaraconsultinggroup.com
Preparation date:	October 17, 2023

2. Device Name

Trade Name of the Device:	Unicare (K-UNICARE-USA)
Common Name:	Nonimplanted electrical continence device
Regulation Name:	Nonimplanted electrical continence device
Regulation Number:	21 CFR 876.5320
Device Class:	II
Panel:	Gastroenterology/Urology
Product Code:	KPI

3. Predicate Devices

510(k) Number:	K191312
Trade Name of the Device:	Perfect PFE

The predicate device has not been subject to a design related recall.

4. Device Description

Unicare is battery powered, single-channel, home-use electrical pelvic floor muscle stimulator. The device is supplied with a non-sterile, reusable (single-patient use) vaginal probe and self-adhesive electrodes which connect to the control unit by cable and plugs. The vaginal probe is inserted into the vagina. The optional self-adhesive electrodes is placed on patients' intact skin and is used for the treatment of only urge urinary incontinence in women. Electrical stimulation is delivered via the vaginal probe or the self-adhesive electrodes to the pelvic floor muscles. This electrical muscle stimulation works as a rehabilitation and training for pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women. The level of electrical stimulation of the Unicare can be controlled by the end user using manual push-button controls. This device is intended for over the counter (OTC) use.

5. Indications For Use

Unicare 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.

6. Comparison of the Technological Characteristics with Predicate Device:

Device & Predicate Device(s):	K230983 (Subject Device)	K191312 (Predicate Device)
Device Name	Unicare	Perfect PFE
Indication for Use	Unicare 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.	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.
Function	Pelvic floor muscle stimulation	Pelvic floor muscle stimulation
Prescription Use Only/OTC	OTC	OTC
Power source	Rechargeable Li-ion 3.7V 80 mAh	2xAA batteries
Maximum Output Current (500Ω load)	99.0 mA +/- 10%	90mA
Maximum current density/electrode (mA/cm^2)	23.35 mA/cm^2	21.4 mA/cm^2
Maximum average power density/electrode (mW/cm^2) @ 500Ω	11.9 mW/cm^2	15.34 mW/cm^2
Output waveform type	Symmetrical Bi-phasic rectangular	Asymmetrical Bi-phasic rectangular
Stimulation frequencies	Stress: 50Hz Urge: 10Hz Mixed: half Stress program & half Urge program Tone: 35Hz	Stress: 50Hz Urge: 10Hz Mixed: half Stress program & half Urge program Tone: 35Hz

Pulse width	Stress: 300µs Urge: 200µs Mixed: half Stress program & half Urge program Tone: 250µs	Stress: 300µs Urge: 200µs Mixed: half Stress program & half Urge program Tone: 250µs
Vaginal probe Electrode surface area (per individual electrode)	4.24 cm^2	4.24 cm^2
Treatment duration	Maximum 20 min	10 or 20 min (default = 20 min)
Treatment Environment	Home use	Home use

As evidenced by the above table, both the subject and the predicate devices have the same intended use, but the subject and predicate devices have different technological characteristics. However, performance testing was conducted on the subject device, and it was established that the differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

7. Non-Clinical Testing

Below is a list of the tests that were performed and successfully completed for the subject device per the below guidance and standards:

- Biocompatibility testing according to ISO 10993-1:2018 - *Biological evaluation of medical devices* — Part 1: Evaluation and testing within a risk management process and FDA Guidance "*Use of International Standard ISO 10993-1*" (2016).

- Electrical Safety testing according to IEC 60601-1: 2020 - *Medical electrical equipment – Basic safety and essential performance*

- Electromagnetic Compatibility testing according to IEC 60601-1-2: 2020 - *General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests*

- IEC 60601-2-10:2016 – *Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*

- Software Verification and Validation Testing according to FDA's Guidance "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"

Additionally, battery service life and performance verification test data were submitted to establish performance and durability of the subject device.

All pre-determined acceptance criteria were met.

8. Conclusions

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.