July 1, 2024

Fotona d.o.o.
Tina Bartolic
Quality Assurance and Regulatory Affairs Specialist
Stegne 7
Ljubljana
SLOVENIA

Re: K234061
Trade/Device Name: StarFormer
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Received: June 4, 2024

Dear Tina Bartolic:

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,

Angel A. Soler-garcia -S

For,
Jessica K. Nguyen, Ph.D.
Assistant Director
DHTB: Division of Reproductive,
Gynecology, and Urology Devices
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)*
K234061

Device Name
StarFormer

Indications for Use *(Describe)*
Fotona StarFormer is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence 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.

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TRADITIONAL 510(K) SUMMARY

1. SUBMITTER INFORMATION

Applicant & Official Correspondent	Ms. Tina Bartolic Quality Assurance and Regulatory Affairs Specialist Fotona d.o.o. Stegne 7, Ljublijana, Slovenia +38615009100 tina.bartolic@fotona.com
Date Prepared	July 01, 2024

2. DEVICE NAME

Trade Name of the Device	StarFormer
Common Name:	StarFormer
Classification Name:	Nonimplanted electrical continence device
Classification Regulation:	21 CFR 876.5320
Device Class:	II
Product Code:	KPI, HIR
Panel:	Gastroenterology/Urology

3. PREDICATE DEVICE IDENTIFICATION

K973096 Neotonus Model 100 Muscle Stimulator system

The predicate device was never subjected to a design related recall.

4. DEVICE DESCRIPTION:

StarFormer is a non-invasive therapeutic device. The device comprises of a magnetic stimulation coil located in the seat of a chair. During the treatment, an alternating electric current is sent into the stimulation coil. The coil builds up a rapidly changing magnetic waves which propagate into the underlying tissue where they induce a secondary electric current which causes muscle contraction in the entire pelvic floor area, increasing the strength and endurance of the pelvic floor. The device consists of a system controller board which also drives the touchscreen and the GUI, a high voltage current power supply and a chair.

5. INDICATIONS FOR USE:

Fotona StarFormer is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in women.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison Element	**Subject Device:** StarFormer	**Predicate Device:** Neotonus Model 100 Muscle Stimulator system
510(k) Number	K234061	K973096
Indications for Use	Fotona StarFormer is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in women.	The neotonus model 1000 muscle stimulator system is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in women.
Function	Pelvic floor muscle stimulation	Pelvic floor muscle stimulation
Principal of action	Initiating action potential of nerves that results in muscle contraction.	Initiating action potential of nerves that results in muscle contraction.
Prescription (Rx) or Over the counter (OTC)	Rx	Rx
Type of energy	Magnetic field	Magnetic field
Energy source	100 -240 V AC, 50 ~ 60 Hz	110 V AC, 50-60 Hz, max 12 A
Type of coil	Single magnetic coil	Single magnetic coil
Type of applicator	Chair	Chair
Position of coil	Center of applicator seat	Center of applicator seat
Patient position during therapy	Sitting position	Sitting position
Type of operation	Continuous	Continuous
Magnetic Field Intensity	1.8 T ± 20%	Up to 2.2 T
Pulse repetition rate	1-80 Hz	1-55 Hz
Step of Frequency Setting	1 Hz	1 Hz
Pulse duration	330 µs	275 µs
Pulse Amplitude	0 – 100 %	0 -100 %
Pulse shape	Sine, biphasic	Sine, biphasic
Therapy time	30 min twice a week for 6-12 weeks	30 min twice a week for 6-12 weeks
User interface	Touch screen	Graphical Display
Operating Temperature	+ 10°C to +25 °C (50 – 77 °F)	+10 to + 30°C (50 – 86 °F)
Number of Output Modes	1	1
Firmware Controlled	Yes	Yes

Environmental Specifications	For indoor use only	For indoor use only
External Exchangeable Fuse	No	Yes
Main Unit Dimensions (WxHxD)	421 x 843 x 630 mm	580 x 170 x 320 mm
Applicator Dimensions (WxHxD)	730 mm x 1050 mm x 740 mm	700 x 1250 x 785 mm
System Weight	50 kg	42.5 kg
Position	Horizontal	Horizontal

As evidenced by the above table, both the subject and the predicate devices have similar 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. SUMMARY OF NONCLINICAL TESTING:

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

- Electrical Safety testing, mechanical strength testing and thermal 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.*
- Software Verification and Validation Testing according to FDA's Guidance (2023) ,*"Content of Premarket Submissions for Device Software Functions | FDA"*
- Cybersecurity testing according to FDA Guidance document (2023), *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions | FDA"*.

Additionally, performance bench data was submitted for device performance i.e., magnetic field strength testing.

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.