September 29, 2023

Fotona d.o.o.
Tina Bartolic
Quality Assurance and Regulatory Affairs
Stegne 7
Ljubljana, 1000, Slovenia

Re: K221274
Trade/Device Name: StarFormer, TightWave
Regulation Number: 21 CFR 21CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, NGX
Dated: April 12, 2022
Received: May 2, 2022

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,

Jitendra V. Virani -S

CDR Jitendra Virani, MS, MBA
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K221274

Device Name
StarFormer

Indications for Use *(Describe)*
Fotona StarFormer is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.
Fotona StarFormer is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes.
-Relaxation of muscle spasm,
-Prevention or retardation of disuse atrophy,
-Increasing local blood circulation,
-Muscle re-education,
-Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
-Maintaining or increasing range of motion.

Fotona StarFormer is indicated for improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen
-Strengthening, Toning and Firming of buttocks and thighs

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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510k Summary

SUBMITTER'S INFORMATION

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Date: April 12, 2022

DEVICE INFORMATION

Device Trade Name:	**StarFormer**
Common name:	Magnetic Stimulator
Classification name:	Stimulator, Muscle, Powered
	21 CFR 890.5850, Class II
Product Code:	IPF, NGX

PREDICATE DEVICES

- Neotonus MS-101 Magnetic Muscle Stimulator System (K973929)
- Johari Digital Healthcare Ltd., TORC BODY (K131291)

DEVICE DESCRIPTION SUMMARY

StarFormer is a non-invasive therapeutic device. The device comprises a magnetic stimulation coil located in the applicator which is placed over the treatment area. During the treatment, an alternating electric current is sent into the stimulation coil. The alternations in the electric current produce electromagnetic field that interacts with the tissues of the human body. The device consists of a system controller board which also drives the touchscreen and the GUI, a high voltage current power supply and an applicator with electromagnetic coil.

INDICATIONS FOR USE

Fotona StarFormer is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.
Fotona StarFormer is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes.

-Relaxation of muscle spasm,
-Prevention or retardation of disuse atrophy,
-Increasing local blood circulation,
-Muscle re-education,
-Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
-Maintaining or increasing range of motion.

Fotona StarFormer is indicated for
improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen

-Strengthening, Toning and Firming of buttocks and thighs

INDICATIONS FOR USE COMPARISON

The indications for use are based on previously cleared indications for the substantially equivalent predicate devices, Neotonus MS-101 Magnetic Stimulator System (K973929) (primary predicate) and Johari Digital Healthcare Ltd., TORC BODY (K131291) (second predicate).

TECHNOLOGICAL COMPARISON

A technical specifications comparison of StarFormer with predicate devices, Neotonus MS-101 Magnetic Stimulator System (K973929) (primary predicate) and Johari Digital Healthcare Ltd., TORC BODY (K131291) (second predicate), is presented in the table below.

Manufacturer	**Neotonus, Inc.**	**Johari Digital HealthCare Ltd.**	**Fotona d.o.o.**	**SE determination**
Device name	**MS-101 Magnetic Muscle Stimulator System** **(Primary predicate)**	**TORC BODY** **(Second predicate)**	**StarFormer** **(Subject device)**	
510 (k) number	**K973929**	**K131291**	**K221274**	
Indications for use	The Neotonus MS-101 Magnetic Muscle Stimulator System is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The Neotonus MS-101 Magnetic Muscle Stimulator System is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: -Relaxation of muscle spasms -Prevention or retardation of disuse atrophy -Increasing local blood circulation -Muscle re-education -Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis -Maintaining or increasing range of motion	TORC BODY is indicated to be used for: - Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. - Strengthening, Toning and Firming of buttocks and thighs.	Fotona StarFormer is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. Fotona StarFormer is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. -Relaxation of muscle spasm, -Prevention or retardation of disuse atrophy, -Increasing local blood circulation, -Muscle re-education, -Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, -Maintaining or increasing range of motion. Fotona StarFormer is indicated for improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen -Strengthening, Toning and Firming of buttocks and thighs	Same
Primary function	Muscle stimulation	Muscle stimulation	Muscle stimulation	Same
Principle of action	Initiating action potential of nerves that results in muscle contraction.	Initiating action potential of nerves that results in muscle contraction.	Initiating action potential of nerves that results in muscle contraction.	Same
Type of energy	Magnetic field	Electrical	Magnetic field	Same as primary predicate, different to second predicate, but the difference does not raise

				different questions on safety and effectiveness therefore not important for SE determination. Principal of action is the same.
Product code regulation	Physical medicine 21 CFR 890.5850 IPF-Stimulator, Muscle, Powered	Physical medicine 21 CFR 890.5850 NGX-Stimulator, Muscle, Powered, For Muscle Conditioning	Physical medicine 21 CFR 890.5850 IPF-Stimulator, Muscle, Powered NGX-Stimulator, Muscle, Powered, For Muscle Conditioning	Same
Pulse repetition rate	1-55 Hz	1-200 Hz	1-80 Hz	No impact. The pulse repetition rate of StarFormer it is not significantly different from the primary predicate. Pulse repetition rate of StarFormer is witih the range of the second predicate. The pulse repetition rates of StarFormer and predicate devices are in the typical clinical range of devices intended for muscle stimulation of up to 200 Hz (from 510(k) database).
Pulse duration	275 µs ± 20%	290 µs	330 µs	No impact. StarFormer`s pulse duration is within the range of the primary predicate (± 20%).  StarFormer`s pulse duration is not significantly different from the second predicate (within 10% range) and has no significant impact on safety and efficacy of the device/therapy. The pulse width of the StarFormer device and the predicate devices are in the typical clinical range of 50 to 500µs. Reference: “The effect

				of stimulus current pulse width on nerve fiber size recruitment patterns" by Robert B. Szlavik and Hubert de Bruin.
Pulse shape	Symmetrical biphasic	Symmetrical biphasic	Symmetrical biphasic	Same
Magnetic field intensity	Up to 2.2 T	NA	Up to 2.2 T	Same
User interface	Graphical Display	Touch screen	Touch screen	Same
Number of Output Modes	1	1	1	Same
Number of Output Channels	1	2	1	Similar, but not significantly different. This information is not relevant for SE evaluation. The number of output channel is related to the device type.
Software/ Firmware/ Microprocessor Control	Yes	Yes	Yes	Same
Timer Ranger	Yes	Yes	Yes	Same
ON Time (device`s duty cycle)	1 s to 30 s	Not publicly available	1 s to 20 s	Clinical outcome is independent of duty cycle. ON/OFF periods are more related to technological limitations, namely overheating of the coil (OFF period). Therefore, this comparison is not relevant for SE evaluation.
OFF Time (device`s duty cycle)	0 s to 60 s	Not publicly available	0 s to 240 s	
Therapy Time	30, 60 min	Up to 60 min	Up to 30 min	Similar. Since the treatment parameters are set individually and are based on a patient pain threshold, this comparison is not relevant for SE evaluation.
Weight	28 kg	/	50 kg	Similar. Not relevant for SE evaluation since it does not affect safety and effectiveness.
Dimenison [W x H x D]	500 x 580 x 230 mm	200 x 150 x 100 mm	421 x 843 x 630 mm	Similar. Not relevant for SE evaluation since it does not affect safety and

				effectiveness.
Housing Materials and Construction	Not publicly available	ABS body enclosure	Device body is made of steel and plastic. Applicators are made of plastics.	This information is not relevant for SE evaluation since no part of the (subject) device comes in the direct contact with the patient.

Technological differences between subject and predicate devices do not raise new type of safety and effectiveness questions and are therefore deemed substantial equivalent.

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY AND CONCLUSIONS

Non-Clinical Summary:

StarFormer has been evaluated via verification and validation tests for conformance to the applicable regulations and safety standards. StarFormer is designed, tested, and will be manufactured in accordance with following standards:

CB Scheme standards:

IEC 60601-1:2005 + A1:2012
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014
Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

IEC 60601-1-6:2010 + A1:2013
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

IEC 62366-1:2015
Medical devices - Application of usability engineering to medical devices.

IEC 62304:2006 + A1:2015
Medical device Software – software life-cycle process.

ISO standards:

ISO 14971:2019
Medical devices — Application of risk management to medical devices

Clinical Summary:

No premarket clinical investigations were conducted since the performance of StarFormer is based on the well-established magnetic stimulation technology and does not carry significant residual risk for patients.

Conclusions:

StarFormer's indications for use and technological characteristics do not raise new type of questions regarding safety and efficacy when compared to both predicates. Based on technical characteristics, design, functional features, performance, and indications for use as listed above, StarFormer is considered to be substantially equivalent to the selected predicate devices.