



March 27, 2025

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

Re: K241785

Trade/Device Name: StarFormer (M008-3T)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: QPL, IPF, NGX
Dated: June 20, 2024
Received: June 20, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

Amber T. Ballard -S

Amber Ballard, PhD

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

Indications for Use

510(k) Number (if known)
K241785

Device Name
StarFormer (M008-3T)

Indications for Use (Describe)

- With handheld applicators:

PMS mode:

Fotona StarFormer is intended for muscle conditioning, used for stimulating muscles including abdomen muscles in order to improve or facilitate muscle performance.

Fotona StarFormer is intended to be used under medical supervision for adjunctive therapy.

Fotona StarFormer is intended for stimulating neuromuscular tissue for bulk muscle excitation in arms, legs, buttocks and thighs for rehabilitative purposes - Prevention of disuse atrophy and increasing local blood circulation.

TENS mode:

Fotona StarFormer is intended to stimulate peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.

Fotona StarFormer is to be used for the temporary relief of pain associated with sore or aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

- With Chair Back applicator:

TENS mode:

Fotona StarFormer is intended to stimulate peripheral nerves in the back for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.

Fotona StarFormer is to be used for the temporary relief of pain associated with sore or aching muscles in the back due to strain from exercise or normal household work activities.

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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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, Ljubljana, Slovenia +38615009100 tina.bartolic@fotona.com
Date Prepared	September 13, 2024
2. DEVICE NAME	
Trade Name of the Device	StarFormer
Common Name:	StarFormer
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Classification Regulation:	882.5890
Device Class:	II
Product Code:	QPL Associated Product Code(s): IPF, NGX
Panel:	Neurology
3. PREDICATE DEVICE IDENTIFICATION	
	K230014 MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption K163393 Hi-Dow Wireless TENS/EMS System (Model HD-SN) K221274 StarFormer
4. DEVICE DESCRIPTION:	
	StarFormer is a non-invasive therapeutic device. The device comprises of a magnetic stimulation coil located in the handheld applicators and in the back 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. This current stimulates neurons and activates muscle contractions. The device consists of a system controller board which also drives the touchscreen and the GUI, a high voltage current power supply, handheld applicators and a chair.
5. INDICATIONS FOR USE:	
	<u>With handheld applicators:</u> PMS mode: Fotona StarFormer is intended for muscle conditioning, used for stimulating muscles



	<p>including abdomen muscles in order to improve or facilitate muscle performance.</p> <p>Fotona StarFormer is intended to be used under medical supervision for adjunctive therapy.</p> <p>Fotona StarFormer is intended for stimulating neuromuscular tissue for bulk muscle excitation in arms, legs, buttocks and thighs for rehabilitative purposes - Prevention of disuse atrophy and increasing local blood circulation.</p> <p>TENS mode:</p> <p>Fotona StarFormer is intended to stimulate peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.</p> <p>Fotona StarFormer is to be used for the temporary relief of pain associated with sore or aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.</p> <p><u>With Chair Back applicator:</u></p> <p>TENS mode:</p> <p>Fotona StarFormer is intended to stimulate peripheral nerves in the back for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.</p> <p>Fotona StarFormer is to be used for the temporary relief of pain associated with sore or aching muscles in the back due to strain from exercise or normal household work activities.</p>
<p>6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE</p>	

Manufacturer	Fotona d.o.o.	Tonica Elektronik A/S	Hi-Dow Electron Technology (Hefei) Inc., Ltd.	Fotona d.o.o.	SE determination
Device name	StarFormer	MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption	Hi-Dow Wireless TENS/EMS (Model HD-5N)	StarFormer	
	SUBJECT DEVICE	PREDICATE DEVICE 1	PREDICATE DEVICE 2	PREDICATE DEVICE 3	
510 (k) number	K241785	K230014	K163393	K221274	
Regulation	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	21 CFR 890.5850	
Product codes	QPL, IPF, NGX	QPL	NUH, NGX	IPF, NGX	Same
Indications for use	<p>With handheld applicators:</p> <p>PMS mode: Fotona StarFormer is intended for muscle conditioning, used for stimulating muscles including abdomen muscles in order to improve or facilitate muscle performance.</p> <p>Fotona StarFormer is intended to be used under medical supervision for adjunctive therapy. Fotona StarFormer is intended for stimulating neuromuscular tissue for bulk muscle excitation in arms, legs, buttocks and thighs for rehabilitative purposes - Prevention of disuse atrophy and increasing local blood circulation.</p> <p>TENS mode: Fotona StarFormer is intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years or older.</p> <p>Fotona StarFormer is to</p>	<p>To stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years or older.</p>	<p>TENS: To be used for the temporary relief of pain associated with sore or aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.</p> <p>EMS: It is intended for muscle conditioning, used for stimulating muscles including abdomen muscles in order to improve or facilitate muscle performance.</p>	<p>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.</p> <ul style="list-style-type: none"> -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. <p>Fotona StarFormer is indicated for improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen</p> <ul style="list-style-type: none"> -Strengthening, Toning and Firming of buttocks and thighs 	<p>Same.</p> <p>The TENS (21 CFR 882.5890) and EMS (21 CFR 882.5890) predicate electric stimulation device (K163393) operates on substantially the same principle as the subject magnetic stimulation device, i.e. by generating electric impulses to stimulate nerves. Depending on the location and intensity of either electrically or magnetically generated electric impulses, the outcome can be primarily nerve stimulation for pain reduction, or nerve-activated muscle contraction.</p>

	<p>be used for the temporary relief of pain associated with sore or aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.</p> <p>With Chair Back applicator:</p> <p>TENS mode: Fotona StarFormer is intended to stimulate peripheral nerves in the back for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years or older .</p> <p>Fotona StarFormer is to be used for the temporary relief of pain associated with sore or aching muscles in the back due to strain from exercise or normal household work activities.</p>				
Anatomical Sites	<p>With handheld applicators:</p> <p>For PMS: Legs, hands and arms, shoulder, abdominal muscles (for muscle conditioning only), waist, buttocks, thighs, calf muscles, middle back and lower back</p> <p>For TENS: Legs, hands and arms, shoulder, waist, buttocks, thighs, calf muscles, middle back and lower back</p> <p>With Chair Back applicator: For TENS mode only: Middle back and lower back</p>	Any area, such as hand, arm, waist, buttock, thigh, calf, back and lower back etc.	<p>TENS: Shoulder, waist, back, upper extremities (arm), and lower extremities (leg)</p> <p>EMS: Muscles including abdominal muscles</p>	Arms and legs, abdomen, buttocks, thighs	Same
Treatment Facilities	Hospitals & clinics (Prescription Use Only)	Hospitals & clinics (Prescription Use Only)	Over-The-Counter Use	Prescription Use Only	Same as predicate devices 1 and 3. Different than predicate device 2. However, professional environment for subject device assures its safe and effective use.
Therapy Time	TENS:	13 min per session (800)			Similar.

	Handheld applicators: Up to 30 min Chair Back applicator: Up to 30 min PMS: Handheld applicators: Up to 30 min	seconds)	45 min	Up to 30 min	Since the treatment parameters are set individually and are based on a patient pain threshold this comparison is not relevant for SE evaluation.
Principle of Action	TENS: Non-invasively stimulate peripheral nerves. PMS: Initiating action potential of nerves that results in muscle contraction.	Non-invasively stimulate peripheral nerves	Not publicly available	Initiating action potential of nerves that results in muscle contraction.	Same
Type of energy	Magnetic field	Magnetic field	Electrical	Magnetic field	Same as predicate devices 1 and 3. Different than predicate device 2. However, this difference does not affect safety and effectiveness since the principal of action is the same, as explained above.
Energy source	100 -240 V AC, 50 ~ 60 Hz	Power supply via Isolation Transformer Power Supply: 120 V~, 50/60Hz	DC 3.7V Lithium Battery	Not publicly available	Similar as predicate devices 1, same as predicate device 3. Different than predicate device 2. Not relevant for SE evaluation since it does not affect safety and effectiveness.
Type of Applicator	TENS: Magnetic handheld coil applicators including coil applicator in the chair backrest. PMS: Magnetic handheld coil applicators	Magnetic coil applicators	Oval electrode pad(gel), 4.5*3cm, 12cm ² ; Rectangular electrode pad(gel), 9*4cm, 36cm ² ; Rectangular electrode pad(gel), 9*6cm, 54cm ² ;	Magnetic coil in applicators	Same as predicate devices 1 and 3. Different than predicate device 2 due to different type of energy used for generating electric impulses.
Type of Operation	TENS: Handheld applicators: Continuous Chair Back applicator: Continuous PMS: Handheld applicators: Continuous	Not publicly available	Continuous/complex; 41~181	Not publicly available	Same
Number of Output Modes	2	Not publicly available	2	1	Same
Number of Output Channels	4	Not publicly available	4	1	Similar. The difference in the number of output channels is not significant for the purposes of substantial equivalence evaluation. This parameter is more related to the specific device design and technology, rather than a fundamental difference in safety or effectiveness.
Magnetic Field Intensity	TENS: Handheld applicators:1.8 T ±	1.15-2.6 T	N/A	Up to 2.2 T	Same as predicate devices 1 and 3. Not applicable for

	20% Chair Back applicator: 1.8 T ± 20% PMS: Handheld applicators: 1.8 T ± 20%				predicate device 2 due to different type of energy applied.
Pulse repetition rate	TENS: Handheld applicators: 1-80 Hz Chair Back applicator: 1-80 Hz PMS: Handheld applicators: 1-80 Hz	MagPro 30 and MagPro30 with MagOption: 0.1-30 Hz MagPro X100 and MagPro X100 with MagOption: 0.1-100 Hz	(TENS) MODE 3: 1.28 Hz (TENS) MODE 4: 1-59.8 Hz (EMS) MODE 1: 52.3 Hz (EMS) MODE 2: 5.8 Hz	1-80 Hz	Same. Not significantly different from the predicate electrical stimulation device 2.
Pulse width	TENS: Handheld applicators: 330 µs ± 10% Chair Back applicator: 330 µs ± 10% PMS: Handheld applicators: 330 µs ± 10%	280-320 µs	TENS & EMS: 100 µs	330 µs	Same as predicate devices 1 and 3. Not significantly different from the predicate electrical stimulation device 2. No significant impact on safety and efficacy of the device/therapy. The pulse width of subject and predicate devices, are in the typical clinical range of 50 to 500µs. <i>Reference: "The effect of stimulus current pulse width on nerve fiber size recruitment patterns" by Robert B. Szlavik and Hubert de Bruin</i>
Pulse Amplitude	TENS: Handheld applicators: 0 – 100 % Chair Back applicator: 0 – 100 % PMS: Handheld applicators: 0 – 100 %	0 – 100 %	N/A	Not publicly available	Same
Waveform	TENS: Handheld applicators: Sine, biphasic Chair Back applicator: Sine, biphasic PMS: Handheld applicators: Sine, biphasic	MagPro 30: Biphasic MagPro30 with MagOption: Biphasic, Monophasic MagPro X100: Biphasic, Biphasic Burst, Monophasic MagPro X100 with MagOption: Biphasic, Halfsine, Biphasic Burst, Monophasic	Pulsed Biphasic	Symmetrical Biphasic	Not significantly different. All devices are capable of biphasic mode.
Maximum Output Power	100% at 15 pps	100% at 15 pps	N/A	Not publicly available	Same
On Cycle Duty Period	1 -20 s	2-800 s	0.1 s	1 -20 s	Similar. The duty cycle range expressed in % as determined by the range of on cycle periods and the range of off cycle reset periods is for the subject device equal to 0.4-100%, which is within the duty cycle range of predicate devices.

Off Cycle Reset Period	0 – 240 s	N/A	0.1 s	0 -240 s	Similar. The duty cycle range expressed in % as determined by the range of on cycle periods and the range of off cycle reset periods is for the subject device equal to 0.4-100%, which is within the duty cycle the range of predicate devices.
User interface	Touch screen	LED display	Not publicly available	Touch screen	Same
Software/Firmware/Microprocessor control	Yes	Yes	Yes	Yes	Same
Operating Temperature	+ 10°C to +25°C (+ 50 °F to 77 °F)	Not publicly available	+ 5°C to + 40°C (41°F~104°F)	Not publicly available	Similar. Falls within the range of Predicate Device 2.
Main Unit Dimensions (WxHxD)	421 x 843 x 630 mm	Not publicly available	Remote: 4.25 (W) x 2.1” (H) x 0.6” (D) Receiver: Φ 2.25” (Diameter) x 0.47” (D)	421 x 843 x 630 mm	Similar. Not relevant for SE evaluation since it does not affect safety and effectiveness.
Applicator Dimensions	Handheld applicators Applicator LARGE coil: 135 - 84 mm (outer - inner diameter) Applicator RADIAL LARGE coil: 135 - 84 mm (outer - inner diameter) Chair Back coil: 135 - 84 mm (outer - inner diameter)	Butterfly coils: 150 mm Circular coils: 110-126 mm Special coils: 160x80 mm	Oval electrode pad(gel): 4.5x3cm, 12cm ² Rectangular electrode pad(gel): 9x4cm, 36cm ² Rectangular electrode pad(gel): 9x6cm, 54cm ²	Not publicly available	Similar. Not relevant for SE evaluation since it does not affect safety and effectiveness.
System Weight	50 kg	Not publicly available	Remote: 2.2 oz Receiver: 0.85 oz	50 kg	Not relevant for SE evaluation since it does not affect safety and effectiveness.
Compliance with Voluntary Standards	<ul style="list-style-type: none"> 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. 	<p>Electrical Safety: IEC60601-1 v3.1 Mechanical Safety: IEC60601-1 v3.1 Chemical Safety: IEC60601-1 v3.1 Thermal Safety: IEC60601-1 v3.1 Radiation Safety: No radiation generated Biocompatibility: ISO 10993 Company complies with ISO 13485</p>	<p>Biocompatibility: All user directly contacting materials are compliance with ISO10993-1:2009/C1 : 2010, ISO10993-5:2009, ISO10993-10:2010.</p> <p>Electrical Safety: IEC 60601-1:2005 (Third Edition) + Corr. 1:2006 + Corr. 2:2007 + A1:2012 (or IEC 60601-1:2012 reprint); IEC 60601-2-10:2012; also complies with ANSI/AAMI ES60601-1:2005 + A1:2012, C1: 2009 and A2: 2010 EN 60601-1: 2006 EN 60601-2-10: 2000 + A1: 2001</p> <p>EMC: IEC 60601-1-2:2007, IEC 60601-1-11:2010 Clause 12, IEC 60601-2-</p>	<p>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</p>	Same

			10:2012 Clause 201.17&202;	Medical devices - Application of usability engineering to medical devices. IEC 62304:2006 + A1:2015 Medical device Software – software life-cycle process ISO 14971:2019 Medical devices — Application of risk management to medical devices	
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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 do not raise different questions of safety or effectiveness.

TENS mode of the StarFormer is substantially equivalent to the MagVenture Pain Therapy predicate device for the relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older using the treatment protocol as outlined in the Applications Manual. Treatment parameters (e.g., repetition rate, pulses per train, number of trains, number of pulses, inter train interval, treatment time) that are not included in the treatment protocol have not been evaluated for effectiveness in the relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.

Treatment protocol:
Treatment level: Individually estimated (% of maximum output power)
Repetition rate: 0.5 pps
Pulses per train: 10
Number of trains: 40
Number of pulses: 400
Inter train interval: 2 s
Treatment time: 13min

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



founding member:



	<p>document (2023), “<i>Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions FDA</i>”.</p> <p>Additionally, performance bench data was submitted for device performance i.e., magnetic field strength testing.</p> <p>All pre-determined acceptance criteria were met.</p>
<p>8.SUMMARY OF CLINICAL TESTING:</p>	<p>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.</p>
<p>9. CONCLUSIONS</p>	<p>Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to predicate devices.</p>