December 19, 2024

QuantumTX Pte. Ltd.
Ivan Goh
CEO
378 Alexandra Road, Alexandra Hospital, Block 29,
CIH Co-Working Space Level 1
Singapore, 159964
Singapore

Re: K240348
Trade/Device Name: Quantum Mitohormesis (QMT) (M2101)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, NGX
Dated: November 21, 2024
Received: November 21, 2024

Dear Ivan Goh:

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,

Jitendra V. Virani -S

CDR Jitendra Virani
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240348

Device Name

Quantum Mitohormesis (QMT) (M2101)

Indications for Use *(Describe)*

Quantum Mitohormesis Medical Device is intended for:
- Stimulating healthy limb muscles to improve and facilitate muscle performance.
- Preventing or retardation of disuse atrophy of muscles.

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 of Safety and Effectiveness for Quantum Mitohormesis (QMT) is provided in accordance with 21 CFR 890.5850.

Date:	12 Jan, 2024
Submitter (Owner):	QuantumTX Pte. Ltd. 298 Tiong Bahru Rd., Central Plaza, #20-06, Singapore168730 ivangoh@quantumtx.com
510(k) Contact Person:	Ivan Goh
Device Trade Name:	Quantum Mitohormesis (QMT) (M2101)
Regulation Number:	21 CFR 890.5850
Regulation Name:	Powered Muscle Stimulator
Classification Panel:	Physical Medicine
Device Class:	Class II
Product Code:	IPF, NGX
Primary Predicate Device:	Bemer Classic & Pro (K151834) **Regulation number:** 21 CFR 890.5850 **Regulation Name:** Powered Muscle Stimulator **Device class:** II **Product code:** NGX **Review panel**: Physical Medicine
Secondary Predicate Device:	Storz Medical MAGNETOLITH Muscle Stimulator (K203710) **Regulation number:** 21 CFR 890.5850 **Regulation Name:** Powered Muscle Stimulator **Device class:** II **Product code:** IPF, NGX **Review panel**: Physical Medicine

Indications for Use:

Quantum Mitohormesis Medical Device is intended for:

- Stimulating healthy muscles to improve and facilitate muscle performance.
- Preventing or retardation of disuse atrophy of muscles.

Description of the Device:

Quantum Mitohormesis (QMT) is a medical device that uses unique pulsed electromagnetic fields for muscle therapy. Users (adults ≥ 22 years old) place one group of muscles in the lower limbs into the field applicator of QMT device, which for a defined duration generates specific electromagnetic fields that stimulates healthy muscles to improve and facilitate muscle performance, and prevents and retards muscle disuse atrophy.

QMT is applied directly to muscles (without direct contact) to stimulate muscle activity. In order to achieve optimized treatment outcome, QMT is applied to muscles on a weekly basis, once or twice a week, with each treatment application lasting a brief 10-minutes.

The device consists of the following high-level components:

a) Base unit, which includes signal generator, power amplifier, and micro-controller unit.
b) Field applicator, which includes electro-magnetic coils generating specific magnetic pulses.
c) User Interface Panel, which allows users to operate the device and display necessary device information.
d) Signal cord.
e) Height and tilt adjustment knobs, which allow users to adjust the height and tilt of field applicator; and

The model numbers included in the submission are indicated below:

Model Name	Model No.	Model Description
Quantum Mitohormesis (QMT)	M2101	Quantum Mitohormesis (QMT) Model M2101, is a medical device that uses unique pulsed electromagnetic fields for muscle therapy. It is intended to stimulate healthy muscles to improve and facilitate muscle performance and prevent or retard disuse atrophy of muscles. The following components are included in the device packing: QMT Device (1), Power Cord (1), Instruction for Use (1).

Comparison to Predicate Devices:

Two predicate devices are selected in this submission for the substantial equivalence discussion of Quantum Mitohormesis.

Predicate device 1: Storz Medical MAGNETOLITH Muscle Stimulator (K203710)

Predicate device 2: Bemer Classic & Pro (K151834)

Parameter	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Comparison**
Device name	**Quantum Mitohormesis**	**Storz Medical MAGNETOLITH Muscle Stimulator**	**Bemer Classic & Pro**	
510(k) number	Not registered	K203710	K151834	
Manufacturer	QuantumTX Pte. Ltd. 298 Tiong Bahru Rd., Central Plaza, #20-06, Singapore168730	Biomed Research, Inc. 3959 Van Dyke Road., Suite 245, Lutz, Florida 33558, United States.	BEMER Int. AG Austrasse 15 Triesen, 9495 Liechtenstein	
Regulation number	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850	Identical
Product code	IPF - Stimulator, Muscle, Powered NGX - Stimulator, Muscle, Powered	IPF - Stimulator, Muscle, Powered NGX - Stimulator, Muscle, Powered	NGX - Stimulator, Muscle, Powered	Identical
Product class	II	II	II	Identical
Intended use/ indication	● Stimulating healthy limb muscles to improve and facilitate muscle performance.	● Relaxation of muscle spasms	● To temporarily increase local blood circulation in healthy leg muscles	Identical

Parameter	Subject Device	Predicate Device 1	Predicate Device 2	Comparison
Device name	**Quantum Mitohormesis**	**Storz Medical MAGNETOLITH Muscle Stimulator**	**Bemer Classic & Pro**	
	● Preventing or retardation of disuse atrophy of muscles.	● 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 ● To stimulate healthy muscles in order to improve and facilitate muscle performance	● To stimulate healthy muscles in order to improve and facilitate muscle performance	
Principle of action	Non- invasive tissue stimulation via magnetic field induction	Non- invasive tissue stimulation via magnetic field induction	Non- invasive tissue stimulation via magnetic field induction	Identical
Clinical use	Prescription use	Prescription use	Over the counter use	
Electrical protection	Class I, B	Class I, B	unknown	Identical
User interface	Buttons	Touch Screen	Touch Screen	Minor difference, no impact on safety and effectiveness.
Firmware controlled	Yes	Yes	Yes	Identical

Parameter	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Comparison**
Device name	**Quantum Mitohormesis**	**Storz Medical MAGNETOLITH Muscle Stimulator**	**Bemer Classic & Pro**	
Type of energy	Magnetic field	Magnetic field	Magnetic field	Identical
Number of outputs	1	1	2	Identical
Number of magnetic coils in the applicator	3	1	unknown	Minor difference, no impact on safety and effectiveness.
Magnetic field intensity	Standard Mode amplitude: 1.0mT ±10% Pro Mode amplitude: 1.3mT ±10%	0.4T ±20% at surface 0.08T ±20% at center of coil	35-100 μT	Minor difference, no impact on safety and effectiveness.
Pulse repetition rate	3.3 kHz	1-10 Hz	10-30 Hz	3.3 kHz electromagnetic pulses are applied as 6 ms bursts with a repetition rate of 50 Hz. Performance testing show comparative safety and effectiveness profile.
Pulse duration	150 μs	125μs ± 20%	10-33 μs	Minor difference, no impact on safety and effectiveness.
Therapy time	10 minutes	10-20 minutes	20 minutes	Identical
Energy source	100 - 240 VAC 50-60Hz	100 - 240 VAC 50-60Hz	100 – 240 VAC, 50/60 Hz	Identical

Parameter	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Comparison**
Device name	**Quantum Mitohormesis**	**Storz Medical MAGNETOLITH Muscle Stimulator**	**Bemer Classic & Pro**	
System dimensions (w×h×d)	565 x 565 x 705mm	454 x 187 x 460 mm	320 x 320 x 70 mm	Difference in dimension does not impact safety and effectiveness.
Ambient temperature	5 – 35 °C	10° – 30°C	10° – 30°C	
Relative humidity	15 – 90 % (non-condensing)	5-55%	unknown	
Environmental specifications	For indoor use only	For indoor use only	For indoor use only	Identical
Biocompatibility	EN ISO 10993-1: 2018 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	Not applicable	EN ISO 10993-1: 2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	
Preclinical testing	• IEC 60601-1:2020: 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 60601-1:2012, (Ed. 3.1): Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. • IEC 60601-1-2: 2014 (4th Ed.): Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic	• IEC/EN 60601-1:2007 Medical Electrical Equipment, Part 1, General Requirements for Safety • IEC 60601-1-2:2014 Medical Electrical Equipment, Part 1-2, General Requirement for Safety, Electromagnetic Compatibility • IEC/EN 60601-1-4:2001 Medical Electrical Equipment, Part 1-4, Collateral Standard:	

Parameter	Subject Device	Predicate Device 1	Predicate Device 2	Comparison
Device name	**Quantum Mitohormesis**	**Storz Medical MAGNETOLITH Muscle Stimulator**	**Bemer Classic & Pro**	
	• IEC TR 60601-4-2: 2016: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems • IEC 60601-1-6: 2020: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability • IEC 62304: 2015: Medical device software - Software life cycle processes	compatibility – Requirements and tests. ● IEC 60601-1-6: 2012 (3.1 Ed.): Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability. ● IEC 62304:2015: Medical Device Software – Software Life Cycle Process.	Programmable electrical medical systems. ● IEC/EN 60601-1-6: 3rd Medical Electrical Equipment, Part 1-6, Usability ● IEC/EN 60601-1-11: 2010 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 ● IEC/EN 62366 Medical devices - Application of usability engineering to medical devices ● EN ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (Overall plan and requirements established	

Parameter	Subject Device	Predicate Device 1	Predicate Device 2	Comparison
Device name	**Quantum Mitohormesis**	**Storz Medical MAGNETOLITH Muscle Stimulator**	**Bemer Classic & Pro**	
			internally, specific tests conducted by 3rd party, see Section 16) ● IEC/EN 62304 Software life cycle processes	

Summary of Non-Clinical Testing:

To demonstrate safety and effectiveness of Quantum Mitohormesis (QMT) and its substantial equivalence to the predicate devices, QuantumTX Pte. Ltd. completed a number of non-clinical performance tests. The QMT device meets all the requirements for overall design, labelling, biocompatibility, software testing, electromagnetic compatibility, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The QMT device passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1: **Passed**
- Electrical safety testing per IEC 60601-1: **Passed**
- Electromagnetic Disturbance testing per IEC 60601-1-2: **Passed**
- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems testing per IEC TR 60601-4-2: **Passed**
- Software verification and validation testing per IEC 62304/FDA Guidance

Summary of Clinical Testing:

There is no clinical data submitted with this submission.

Conclusion:

Based on the results of risk assessments, biocompatibility evaluation, software, performance testing, electromagnetic compatibility and electrical safety testing, and compliance with recognized standards, it is determined that any differences between the Quantum Mitohormesis (QMT) device and the predicate devices do not raise new safety or effectiveness issues. Quantum Mitohormesis device is substantially equivalent to the predicate devices.