August 28, 2025

Syrma Johari Medtech Limited
Sabyasachi Nath
Senior General Manager-QARA
G-582-584, EPIP, Boranada
Jodhpur, Rajasthan 342012
India

Re: K251594
Trade/Device Name: truFlex
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: July 31, 2025
Received: July 31, 2025

Dear Sabyasachi Nath:

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251594

Please provide the device trade name(s).

truFlex

Please provide your Indications for Use below.

truFlex 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 arms, buttocks, thighs, and calves
• Relaxation of muscle spasms
• Prevention or retardation of disuse atrophy
• Increasing local blood circulation
• Muscle re-education
• Maintaining or increasing range of motion
• Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
• Stimulation of neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes
• To be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions

The device safety and efficacy was demonstrated by performance data and a comparison of technical characteristics between the modified device and the predicate device.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Syrma Johari MedTech Limited.
(Formerly known as Johari Digital Healthcare Limited)

Registered Office
G-582-584, EPIP,
Boranada, Jodhpur - 342012
Rajasthan, BHARAT
Contact: 0291-2942943

Design Center
402, Tower 2, WTC,
Kharadi, Pune - 411014
Maharashtra, BHARAT

CIN: U45201RJ1995PLC009997

510(k) Summary

K251594

Submitter Information:

Name	Syrma Johari Medtech Limited
Address	G-582- 584 EPIP, Boranada, Jodhpur – India – 342012
Name of Contact Person	Sabyasachi Nath Sr. GM-QARA, Syrma Johari Medtech Limited G-582- 584 EPIP, Boranada, Jodhpur – India – 342012
Phone Number	+91- 9251617039
Summary Preparation Date	Dec 03, 2024

Name of Subject Device:

Device Name	truFlex Muscle Stimulator
Device Trade or Proprietary Name	truFlex
Common or Usual Name	Powered Muscle Stimulator
Classification Name	Stimulator, Muscle, Powered, For Muscle Conditioning
Classification Regulation	21 CFR 890.5850, Class II
Classification Product Code	NGX, IPF

Legally marketed Predicate Device 1

Device Trade Name	truSculpt Flex
Classification Name	Stimulator, Muscle, Powered, For Muscle Conditioning
510(K) No	K212866
Classification Product Code	NGX
Address and Registration	Syrma Johari Medtech Limited (formerly known as Johari Digital healthcare limited) G-582, 584 EPIP, Boranada, Jodhpur – India – 342012

Legally marketed Predicate Device 2

Device Trade Name	accufit
Classification Name	Stimulator, Muscle, Powered, For Muscle Conditioning
510(K) No	K233926
Classification Product Code	NGX, IPF
Address and Registration	Mettler Electronics Corporation 1333 South Claudina Street Anaheim, CA 92805

Legally marketed Predicate Device 3

Syrma Johari MedTech Limited.
(Formerly known as Johari Digital Healthcare Limited)

Registered Office
G-582-584, EPIP,
Boranada, Jodhpur - 342012
Rajasthan, BHARAT
Contact: 0291-2942943

Design Center
402, Tower 2, WTC,
Kharadi, Pune - 411014
Maharashtra, BHARAT

CIN: U45201RJ1995PLC009997

Device Trade Name	Btl-899ms
Classification Name	Powered Muscle Stimulator
510(K) No	K240234
Classification Product Code	NGX, IPF
Address and Registration	BTL Industries, Inc, North America 362 Elm Street Marlborough, Massachusetts 01752

Device Description

truFlex is an electrical muscle stimulator, which generates electrical impulses that are delivered through electrodes on the skin in direct proximity to the muscles to be stimulated. The device contracts muscles rhythmically to achieve the intended use.

truFlex consists of a console with a touchscreen control panel and eight handpiece pairs. All system functions are controlled through the console. During a treatment session, one or more handpiece pairs are secured to the patient using disposable hydrogel pads and transparent silicone belts, and electrical stimulation is delivered to the treatment area at the selected treatment mode and intensity.

The fundamental scientific technology has not changed in the modified device. Changes are solely considered for addition of indication for use. The modified device generates the same stimulation to contract the muscles rhythmically to achieve the intended use.

The clinician can increase or decrease the intensity as per the desired stimulation. While modified device, complete care and considerable measures have been taken to retain its safety and effectiveness. The truFlex device complies with voluntary standards.

The modified device, as described in this submission, have only addition of the indication for use and name the devcie
The device has two treatment types:

- Classic - In Classic mode, the treatment duration is 45 minutes.
- flex+ - In flex+ mode, the treatment duration is 15 minutes.

For ease of use and operation for the clinicians, we have 3 modes (suggestive):

- **PREP mode** creates a twisting motion to warm up and stretch the muscles and to slowly build a tolerance to muscle contractions. PREP mode is available for Classic treatments only.

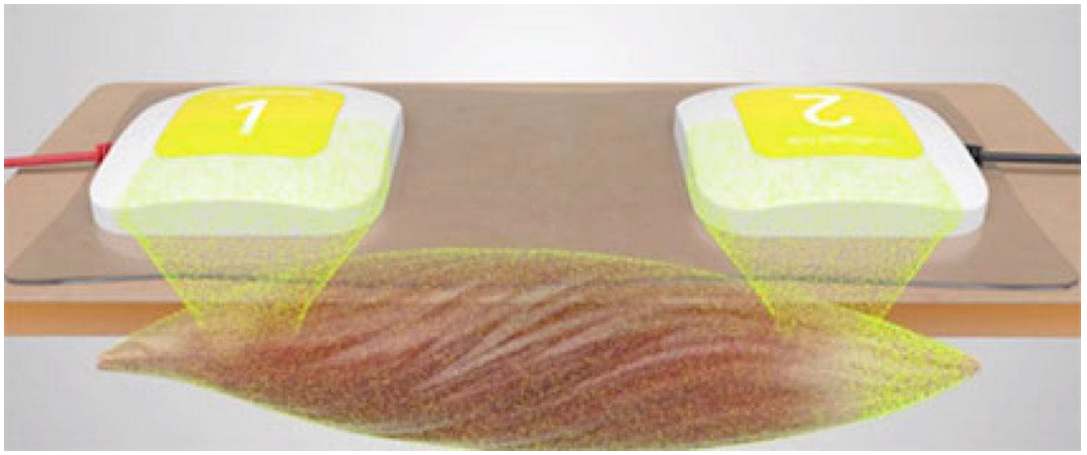


Fig:- Prep Mode

• **TONE mode** contracts the muscles, holds it, and then relaxes to increase strength and muscle endurance. TONE mode is available for Classic and flex+ treatments.

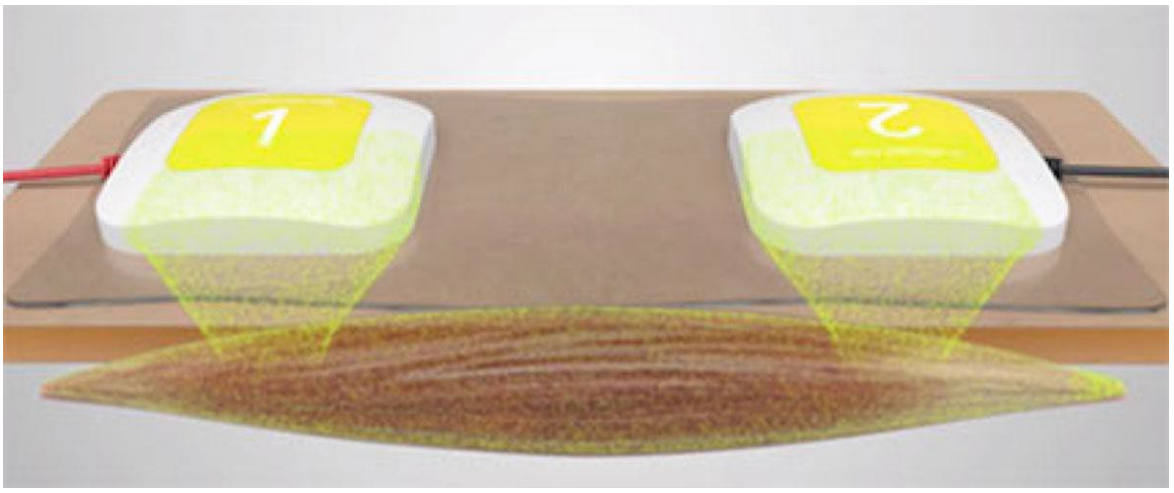


Fig:- Tone Mode

• **SCULPT mode** uses fast, sequential contractions of the muscles which lead to toning and firming. SCULPT mode is available for Classic and flex+ treatments

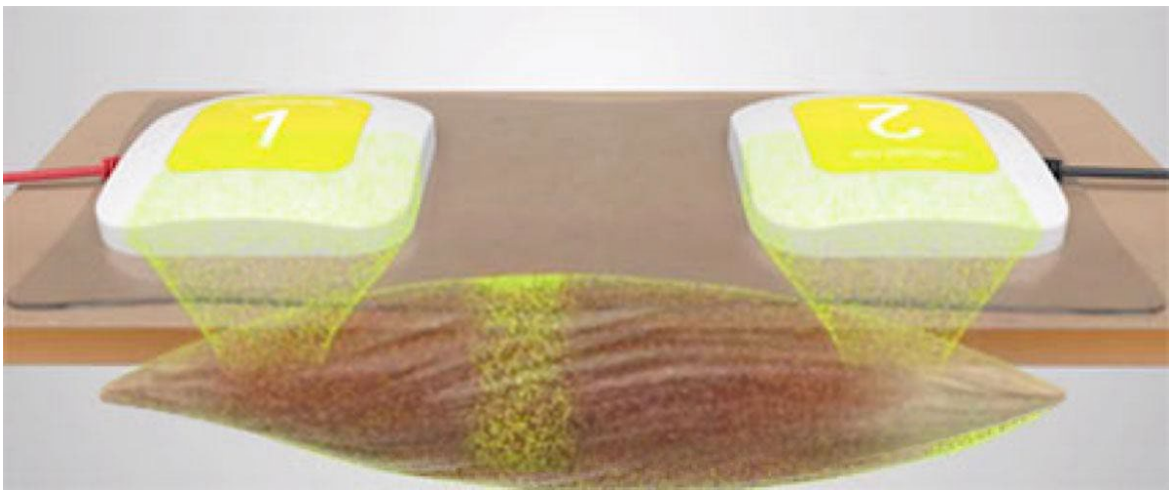
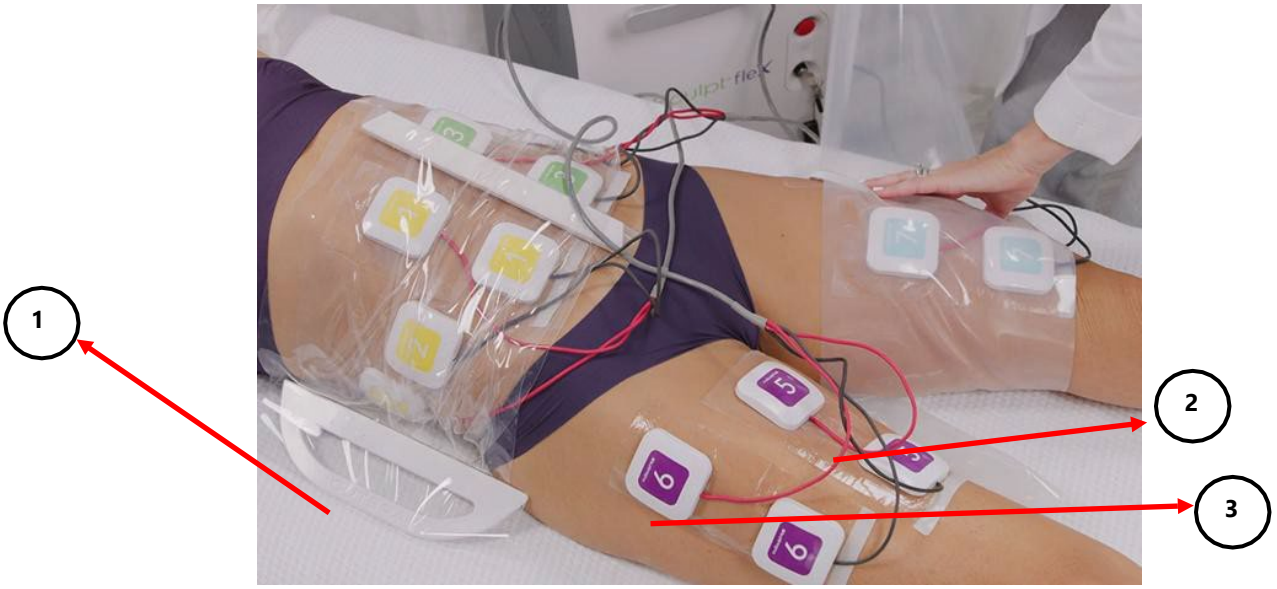


Fig:- Sculpt Mode

truflex in action- Interaction with patient

The device contracts muscles rhythmically to achieve the intended use of strengthening, firming, and toning the muscles of the abdomen, thighs, and buttocks, and Relaxation of muscle spasms, Prevention or retardation of disuse atrophy, Increasing local blood circulation, Muscle re-education, Maintaining or increasing range of motion, Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Stimulation of neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes and symptomatic relief and management of chronic long-term intractable pain



Where

1. Reusable silicone belts (cummerbunds)
2. Electrodes (Handpiece)
3. Adhesive hydrogel pads

The device generates electrical stimulation to contract the muscles rhythmically to achieve the its intended use.

While modified the device, complete care and considerable measures have been taken to retain its safety and effectiveness. The truFlex device complies with voluntary standards.

Indication for Use

truFlex 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 arms, buttocks, thighs, and calves
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Stimulation of neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes
- To be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions

The device safety and efficacy was demonstrated by performance data and a comparison of technical characteristics between the modified device and the predicate device.

Substantial Equivalence- The intended use and indication for use of the modified device are the same as the predicate device (1. truSculpt Flex K212866. 2. Accufit, K233926, 3. emSculpt NEO BTL 899MS K240234)).

Summary of the technological characteristics of the device compared to the predicate

A comparison given below identifies all the changes between the modified and the predicate device:

Syrma Johari MedTech Limited.
(Formerly known as Johari Digital Healthcare Limited)

Registered Office
G-582-584, EPIP,
Boranada, Jodhpur - 342012
Rajasthan, BHARAT
Contact: 0291-2942943

Design Center
402, Tower 2, WTC,
Kharadi, Pune - 411014
Maharashtra, BHARAT

CIN: U45201RJ1995PLC009997

Basic Device Characteristics – Comparison with Predicate Device

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
Device Name	**truFlex**	**truSculpt Flex**	**Accufit**	**emSculpt NEO BTL-899MS**	NA
510(k)	Not Assigned	K212866	K233926	K240234	NA
Manufacturer	Syrma Johari Medtech Limited (Formerly Known as Johari Digital Healthcare Limited)	Syrma Johari Medtech Limited (Formerly Known as Johari Digital Healthcare Limited)	Mettler / Lutronic Corporation	BTL Industries, Inc.	NA
Regulation Number	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850	Subject device is identical to all Predicate Devices
Regulation Name	Powered Muscle Stimulator	Powered Muscle Stimulator	Powered Muscle Stimulator	Powered Muscle Stimulator	Subject device is identical to all Predicate Devices
Regulatory Class	Class II	Class II	Class II	Class II	Subject device is identical to all Predicate Devices
Product Code	NGX, IPF	NGX	NGX, IPF	NGX, IPF	Subject device is identical to all Predicate Devices
Panel	Physical Medicine	Physical Medicine	Physical Medicine	Physical Medicine	Subject device is identical to all Predicate Devices

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
Indications for Use	• Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Strengthening, toning and firming of arms, buttocks, thighs, and calves • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Maintaining or increasing range of motion • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Stimulation of neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes • To be used under medical supervision for	• Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Strengthening, toning and firming of buttocks & thighs.	• Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increase local blood circulation • Muscle re-education • Maintaining or increasing range of motion • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas.	The BTL-899MS device is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, toning and firming of buttocks, thighs and calves. • Improvement of muscle tone and firmness, for strengthening muscles in arms. The BTL-899MS device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The BTL-899MS device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes.	**Subject Device Indication for Use has been derived from Predicate Devices 1, 2, 3**

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
	adjunctive therapy for the treatment of medical diseases and conditions			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	
Power Source	100-240AC, 50/60Hz, 75VA	100-240AC, 50/60Hz, 75VA	100-240VAC, 50/60Hz, 1.0A	100 – 240 V AC, 50–60 Hz	Subject device is identical to all Predicate Devices
Therapeutic Modality	Electrical muscle stimulator	Electrical muscle stimulator	Electrical muscle stimulator	Electromagnetic stimulation accompanied by bipolar radiofrequency	Subject device is identical to Predicate Devices 1 and 2
Treatment Output Mode	Electrode	Electrode	Electrode	Electrode	Subject device is identical to all Predicate Devices
Method of Line Current Isolation	The AC Power supply is converted to DC Power supply through a medical-grade PSU, which has isolation of 2XMOPP (IEC60601-1)	The AC Power supply is converted to DC Power supply through a medical-grade PSU, which has isolation of 2XMOPP (IEC60601-1)	Double Insulated Wire Non-Conductive Enclosure	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
	Isolation through transformer between device and patient	Isolation through transformer between device and patient			
Measured Patient Leakage					
Normal Condition (µA)	Less than 100µA	Less than 100µA	Less than 100µA	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3
Single Fault Condition (µA)	Less than 300µA	Less than 300µA	Less than 100µA	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3
Number of Output Modes	03	03	04	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3
Number of Output Channels	4	4	2	2	Subject Device is identical to Predicate Device 1, and Similar to Predicate Devices 2 and 3
Regulated Current or Voltage	Trans Conductance	Trans Conductance	Current = 100mA maximum	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
Software / Firmware / Microprocessor Control	Yes	Yes	Yes	Yes	Subject device is identical to all Predicate Devices
Automatic Over Current Trip	Yes	Yes	Yes	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3
Automatic No Load Trip	No	No	Yes	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3
Automatic Shut Off	Yes	Yes	Yes	Yes	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3
User Override Control	Yes	Yes	Yes	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3
Indicator Display	Yes	Yes	Yes	Yes	Subject device is identical to all Predicate Devices

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
On / Off Status	Yes	Yes	Yes	Yes	Subject device is identical to all Predicate Devices
Voltage / Current Level	Yes	Yes	Yes	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3
Timer range	15, 30, 45 Mins	15, 30, 45 Mins	15, 30, 45 Mins	up to 30 mins	Subject device is identical to all Predicate Devices

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
Compliance: Voluntary Standards	• IEC 60101-1, an International Standard on Medical electrical equipment general requirements for safety (FDA Recognition List Number 19-4); • IEC 60601-1-2, an International Standard on Medical electrical equipment, electro-magnetic compatibility (FDA Recognition List Number 19-8); • IEC 60601-2-10 an International Standard on Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle	• IEC 60101-1, an International Standard on Medical electrical equipment general requirements for safety (FDA Recognition List Number 19-4); • IEC 60601-1-2, an International Standard on Medical electrical equipment, electro- magnetic compatibility (FDA Recognition List Number 19-8); • IEC 60601-2-10 an International Standard on Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (FDA Recognition List Number 17-16), and • IEC 62304 Medical device software - Software life cycle processes (FDA	• IEC 60101-1, an International Standard on Medical electrical equipment general requirements for safety (FDA Recognition List Number 19-4); • IEC 60601-1-2, an International Standard on Medical electrical equipment, electro- magnetic compatibility (FDA Recognition List Number 19-8); • IEC 60601-1-6, an International Standard on Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (FDA Recognition List Number 5-132), • IEC 60601-2-10 an International Standard on Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability IEC 62304 Medical device software – Software life cycle processes ISO 14971	Subject device is identical to all Predicate Devices

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
	stimulators (FDA Recognition List Number 17-16), and • IEC TR 60601-4-2 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems (FDA Recognition List Number 19-19). • IEC 62304 Medical device software - Software life cycle processes (FDA Recognition List Number 13-79)	Recognition List Number 13-79)	nerve and muscle stimulators (FDA Recognition List Number 17-16), and • IEC TR 60601-4-2 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems (FDA Recognition List Number 19-19). • IEC 62304 Medical device software - Software life cycle processes (FDA Recognition List Number 13-79) • Cytotoxicity per ISO 10993-5:2009 • Skin sensitization per ISO 10993-10:2021	Medical devices – Application of risk management to medical devices ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	
Compliance: 21CFR898	Yes	Yes	Yes	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
Weight	32.66	32.66	27Kg	70Kg	Subject Device is identical to Predicate Devices 1 and 2, but similar to Predicate Devices 3
Dimensions (mm) W x L x H	445 x 356 x 1016	445 x 356 x 1016	452 x 582 x 1101	592 x 730 x 985	Subject Device is identical to Predicate Devices 1 and 2, but similar to Predicate Devices 3
Housing, Materials and Construction	ABS Plastic	ABS Plastic	ABS Plastic	Data not available	Subject device is identical to Predicate Devices 1,2 but no Data is available for Predicate Device 3
Medical Equipment Classification	Type BF	Type BF	Type BF	Type BF	Subject device is identical to all Predicate Devices
Principle of Operations	EMS Mode: truFlex uses Electrical Muscle Stimulation (EMS) to deliver electrical pulses to the targeted muscle groups. These pulses mimic natural nerve signals, causing muscle contractions that lead to strengthening, toning, and	truSculpt flex is an electrical muscle stimulator, which generates electrical impulses that are delivered through electrodes on the skin in direct proximity to the muscles to be stimulated.	The principle of operation of the accufit device is to provide direct electrical stimulation of muscles which produces muscle contractions in and around the area of the treatment electrodes.	HIFEM® Mode: High-Intensity Focused Electromagnetic (HIFEM®) technology induces supramaximal contractions in targeted muscles. These contractions go beyond voluntary effort, promoting muscle hypertrophy and increased strength.	Subject Device is identical to Predicate Devices 1 and 2 but not matching with Predicate Device 3

Characteristics	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
	increased local circulation. Rehabilitation Mode: truFlex operates in a low-frequency EMS mode designed for therapeutic purposes, such as muscle re-education, prevention of disuse atrophy, and relief of muscle spasms.			RF Mode: Radiofrequency (RF) energy is simultaneously applied to heat the fat layer, leading to lipolysis (fat cell destruction). RF energy also enhances blood flow and optimizes muscle stimulation during treatments.	

Comparison of output specification

S.No.	Parameters	Subject device - truFlex	Predicate 1 - truSculpt Flex - K192039	Predicate 2 - Accufit - K233926	Predicate 3 - emSculpt NEO - K240234
1	Type of mode	3 (Prep, Tone, Sculpt)	3 (Prep, Tone, Sculpt)	2	N/A
2	Waveform	Symmetrical Biphasic	Symmetrical Biphasic	2 (Biphasic and Interferential (4P))	Symmetrical Biphasic Pulsed Magnetic (HIFEM)
3	Shape	Step Sine Wave	Step Sine Wave	Square (Biphasic) Sinusoidal (Interferential (4P))	Sine Wave
4	Maximum Output Voltage	100 Vpp @ 500Ω 125 Vpp @ 2KΩ 133 Vpp @ 10KΩ	100 Vpp @ 500Ω 125 Vpp @ 2KΩ 133 Vpp @ 10KΩ	104 @ 500Ω; 197 @ 2kΩ; 178 @ 10kΩ	100 Vpp @ 500Ω
5	Maximum Output Current	200 mA @ 500Ω 62.5 mA @ 2KΩ 13 mA @ 10KΩ	200 mA @ 500Ω 62.5 mA @ 2KΩ 13 mA @ 10KΩ	106 @ 500Ω; 49 @ 2kΩ; 9 @ 10kΩ	251 mA @ 500Ω

S.No.	Parameters	Subject device - truFlex	Predicate 1 - truSculpt Flex - K192039	Predicate 2 - Accufit - K233926	Predicate 3 - emSculpt NEO - K240234
6	Pulse Width	125 µs (±10%) @ 500Ω	125 µs (±10%) @ 500Ω	40-800 µSec	AP-C-1 – 280 µs ±20% or AP-C-2 – 190 µs ±20%
7	Frequency	Channel1: 4000 Hz (±10%) Channel2: 4001–4100 Hz (±10%) Resultant: 1–100 Hz	Channel1: 4000 Hz (±10%) Channel2: 4001–4100 Hz (±10%) Resultant: 1–100 Hz	1-200 Hz	1-150 Hz
8	Beat Frequency	1–100 Hz	1–100 Hz	1-200 Hz	1-150 Hz
9	Multiphasic Waveform	Yes 125 µs	Yes 125 µs	Yes	Yes
10	Net Charge	0 µC @ 500Ω	0 µC @ 500Ω	Net Charge = 0 µC (Biphasic & Interferential (4P) pulses are symmetrical about 0V)	0 µC (current is symmetrical)
11	Maximum Phase Charge	12.5 µC	12.5 µC	42.4 µC, 500 Ω	Unknown
12	Maximum Current Density	2.88 mA/cm²	2.88 mA/cm²	5.13 mA/cm2 , 500 Ω	3.6 mA/cm2 (10 cm diameter coil applicator)
13	Maximum Power Density	0.144 W/cm²	0.144 W/cm²	0.043 W/cm², 500 Ω	Unknown
14	ON Time	0-6 seconds	0-6 seconds	Biphasic 1 – 240 seconds, Interferential (4P) NA	Programmable
15	OFF Time	0-4 seconds	0-4 seconds	Biphasic 1 – 240 seconds, Interferential (4P) NA	Programmable
16	Additional Features	Sweep Frequency 1–100 Hz	Sweep Frequency 1–100 Hz	N/A	HIFEM, touchscreen, dual applicators

There are no changes to the subject device in terms of its fundamental scientific principles, performance specifications, or operation when compared to the FDA-cleared predicate devices (TruSculpt Flex (K212866), Accufit (K233926) and emSculpt NEO BTL 899MS (K240234)).

In the subject device, truFlex, the only modification is an expanded indication for use, which is already covered by the FDA-cleared predicate devices (TruSculpt Flex (K212866), Accufit (K233926) and emSculpt NEO BTL 899MS (K240234)).

Furthermore, there are no technological differences, fundamental scientific principles, performance specifications, indication for use and operation between the FDA-cleared predicate and subject devices that raise concerns regarding safety or effectiveness.

The observed deviations in values in table of Substantial Equivalence remain within acceptable limits as per: "Guidance Document for Powered Muscle Stimulator 510(k)s" (issued June 9, 1999) and ANSI/AAMI NS4:2013 (R2017) standard for electrical stimulators. Thus, the modifications do not impact on the overall safety and effectiveness of the device.

Non-clinical Testing (Performance, Bench Testing)

Standard Number	Standard Description	FDA recognition number
ISO 14971: 2019	Medical devices -- Application of risk management to medical devices	5-125
IEC60601-1:2005+AMD:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-49
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	19-36
IEC 60601-2-10	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	17-16
IEC 60601-1-6: 2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-132
IEC 62304:2015	Medical device software - Software life cycle processes	13-79
ISO 10993-1: 2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2-258
ISO 10993-5: 2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	2-245
ISO 10993-10: 2021	Biological evaluation of medical devices Part 10: Tests for skin sensitization	2-174
IEC TR 60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	19-19

CONCLUSION

The subject device, truFlex, is substantially equivalent to the FDA-cleared predicate devices TruSculpt Flex (K212866), Accufit (K233926) and emSculpt NEO BTL 899MS (K240234) in terms of

fundamental scientific principles, technology, performance, operation, and indications for use. Based on this, the truFlex device meets the criteria for substantial equivalence under 510(k) clearance, demonstrating no new concerns regarding safety or effectiveness compared to the predicate devices