December 3, 2022

Johari Digital Healthcare Limited
Pooja Johari
Founder and Director Marketing
G-582, 584 EPIP, Boranda
Jodhpur, Rajasthan 342012
India

Re: K212866
Trade/Device Name: truSculpt flex
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 28, 2022
Received: November 4, 2022

Dear Pooja Johari:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Heather L. Dean -S

Heather Dean, Ph.D.
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

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)*
K212866

Device Name
truSculpt flex

Indications for Use *(Describe)*
truSculpt flex 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 & 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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510 (k) Summary

Device Name	truSculpt flex muscle stimulator
Submitters name/ contact details	Nisha Johari Johari Digital Healthcare Ltd G-582- 584 EPIP, Boranada, Jodhpur – India – 342012 Contact number: + 91-9829954228
Summary Preparation Date	28-Oct-2022
Device Trade Name	truSculpt flex
Device / Proprietary Name	truSculpt flex
Common Name	Stimulator, Muscle, Powered, for Muscle Conditioning
Classification Name	Powered Muscle Stimulator, Stimulator, Muscle, Powered, For Muscle Conditioning
Classification Regulation	21 CFR 890.5850, Class II
Classification Product Code	NGX

Legally marketed Predicate Device

Device Trade Name	Torc Body
Classification Name	Powered Muscle Stimulator, Stimulator, Muscle, Powered, For Muscle Conditioning
510(K) No	K192039
Address and Registration	Johari Digital Healthcare Ltd G-582, 584 EPIP, Boranada, Jodhpur – India – 342012
Contact Person:	Nisha Johari
FDA Registration	8040537

Device Description

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 device contracts muscles rhythmically to achieve the intended use of strengthening, firming, and toning the muscles of the abdomen, thighs, and buttocks.

truSculpt flex 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 ease of use for the clinicians. The modified device generates the same stimulation to contract the muscles rhythmically to achieve the intended use of strengthening, firming, and toning the muscles of the abdomen, thighs, and buttocks.

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

The modified device, as described in this submission, is an upgrade from its previous version. Modifications include the addition of two outputs; change in electrode size and type; addition of adhesive hydrogel pads and reusable silicone belts; and renaming of treatment modes.

With respect to the previously cleared device, the modified 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.

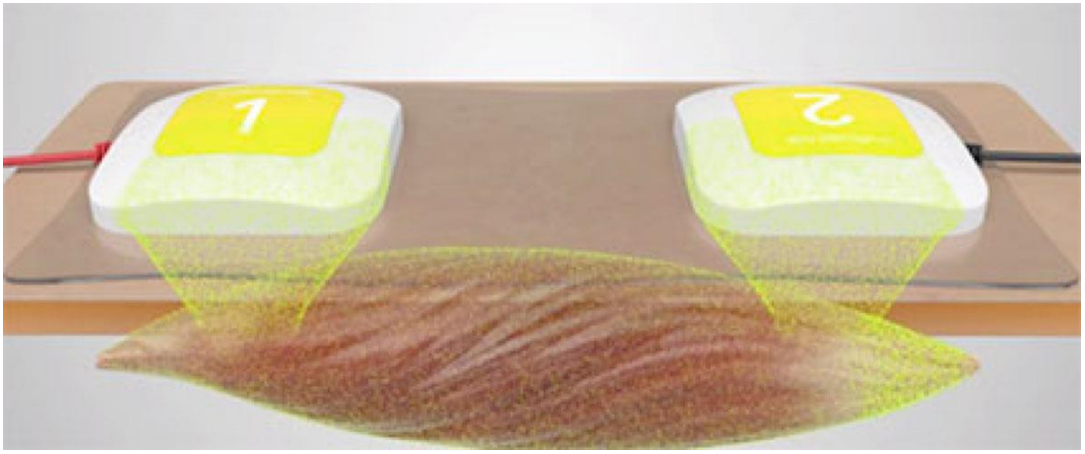


Fig:- Prep Mode

• **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.

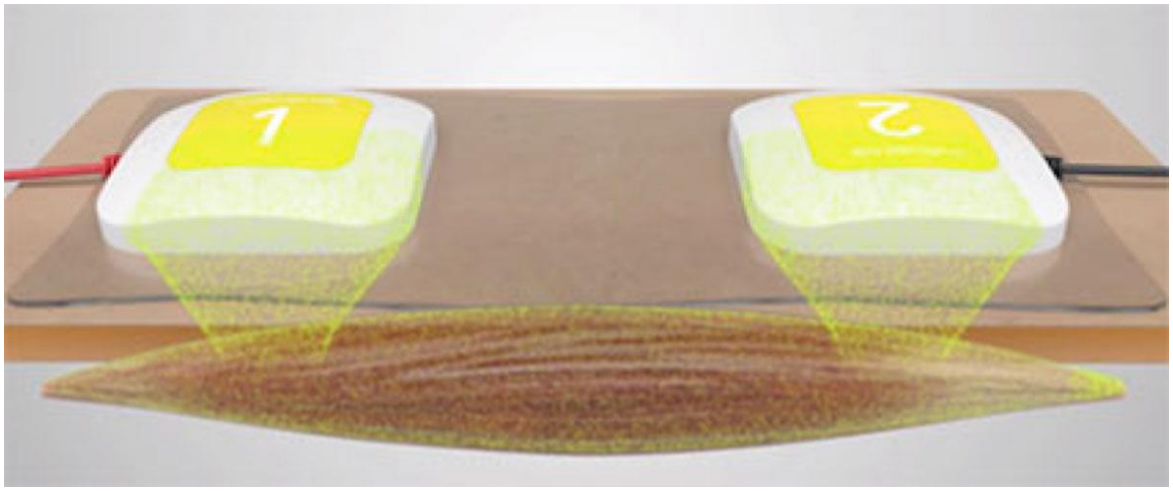


Fig:- Tone Mode

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

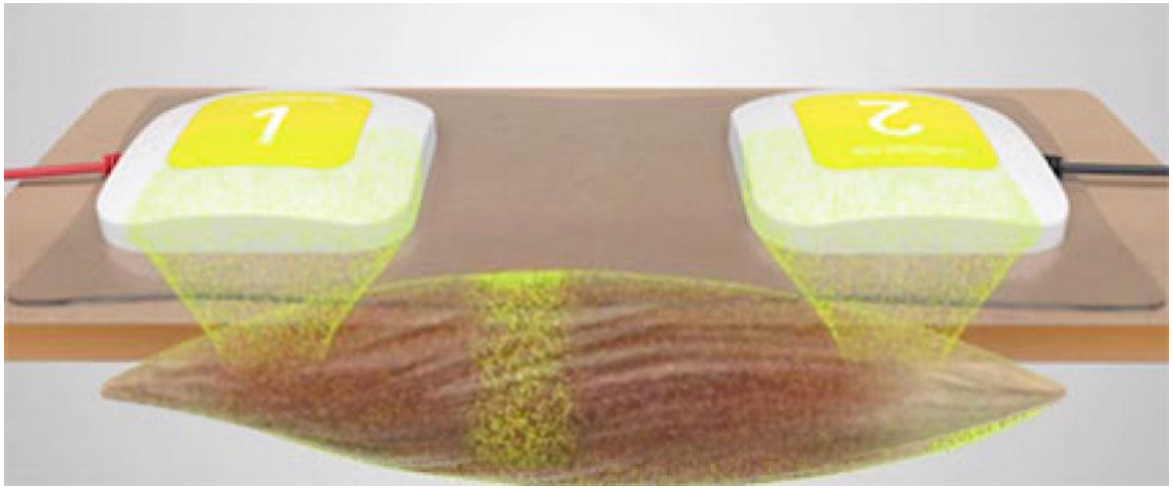
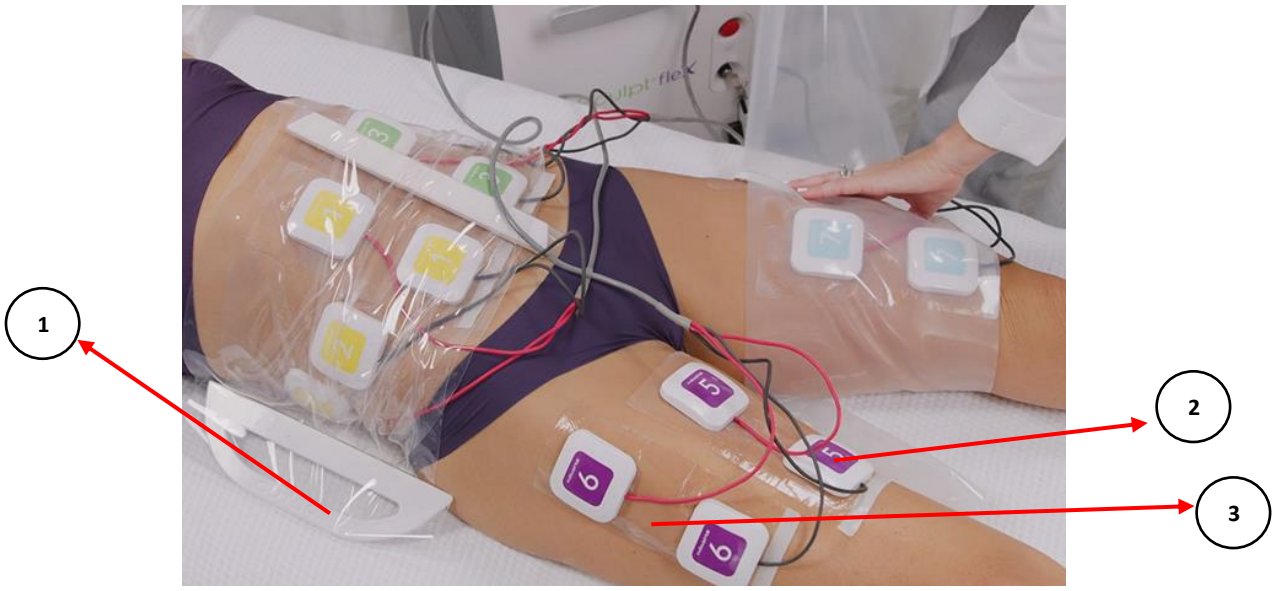


Fig:- Sculpt Mode

truSculpt flex 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.



Where

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

The modified device generates electrical stimulation to contract the muscles rhythmically to achieve the intended use of strengthening, firming, and toning the muscles of the abdomen, thighs, and buttocks.

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

Intended Use

truSculpt flex 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 & thighs.

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 (Torc Body , K192039).

Comparison of Technological Characteristics

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

Basic Device Characteristics – Comparison with Predicate Device

Device Features	Modified device	Predicate Device	Comparison
510(K) Number	**K212866**	**K192039**	N/A
Device Name, Model	truSculpt flex	Torc Body	**Design revision updated**
Manufactured For	7e Wellness Corporation	7e Wellness Corporation	Identical
Manufactured By	Johari Digital Healthcare Ltd.	Johari Digital Healthcare Ltd.	Identical
Classification Name	Powered muscle stimulator	Powered muscle stimulator	Identical
Product Code	NGX	NGX	Identical
Regulation Number	21 CFR 890.5850	21 CFR 890.5850	Identical
Panel	Physical Medicine	Physical Medicine	Identical
Class	Class II	Class II	Identical
Prescription/OTC	Prescription	Prescription	Identical
Indication for use	• Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Strengthening, toning and firming of buttocks & thighs.	• Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Strengthening, toning and firming of buttocks & thighs.	Identical
Target population	It is to be used by adults only	It is to be used by adults only.	Identical
Power source	100-240AC, 50/60Hz, 75VA	100-240AC, 50/60Hz, 75VA	Identical
Method of Line Current Isolation	(a) AC Power supply is converted to DC Power supply through a medical-grade PSU, which has isolation of 2XMOPP (IEC60601-1) (b) Isolation thru transformer between device and patient	(a) AC Power supply is converted to DC Power supply through a medical-grade PSU, which has isolation of 2XMOPP (IEC60601-1) (b) Isolation thru transformer between device and patient	Identical

Device Features	Modified device	Predicate Device	Comparison
Patient Leakage Current Normal condition Single Fault condition	Normal condition = less than 100µA Single fault condition = less than 300µA	Normal condition = less than 100µA Single fault condition = less than 300µA	Identical
Components	Main unit, 8 Stainless steel reusable electrodes pairs (16 electrodes) 4 electrode lead wires 1 AC Power Cord 4 Hydrogel pads 2 reusable silicone belts (cummerbunds)	Main unit, 8 self adhesive electrodes , 4 electrode lead wires, 1 AC Power Cord	**Modified;** -The modified device has two additional outputs (4 channels), hence the number of electrodes has been increased from 8 to 16. - The modified device has stainless steel electrodes, which do not have any expiry and are more reliable, cost-effective, and environmentally friendly than single-use electrodes. -Hydrogel pads are being added to facilitate attachment of electrodes to patient's skin and to enhance energy coupling. - Silicone belts are being added to secure

Device Features	Modified device	Predicate Device	Comparison
			electrodes in place.
Display	12” LCD	12” LCD	Identical
Number of Output Modes	03 (Prep, Tone, Sculpt)	03 (Classic Vector, Power Sequence, Dynamic Rotation)	**Modified;** Renamed treatment modes for usability.
Number of Output Channels Synchronous or Alternating?	4 Synchronous (a) Outputs 1 to 4 are completely isolated. Only power supply and ground are common.	2 Synchronous (a) Outputs 1 to 2 are completely isolated. Only power supply and ground are common.	**Modified** The number of outputs is being increased from two to four to provide enhanced customization and flexibility to the clinician. The modified device has been tested against EMI/EMC & safety standards as per the IEC 60601-1 requirements. All the test reports are available under section 017_Electromagnetic Compatability & Electrical Safety
Method of Channel Isolation	Transformer	Transformer	Identical
Regulated Current or Regulated Voltage	Tran conductance	Tran conductance	Identical
Software/Firmware/ Microprocessors Controls?	YES	YES	Identical
Automatic Overload Trip?	YES	YES	Identical
Automatic No-Load	NO	NO	Identical

Device Features	Modified device	Predicate Device	Comparison
Trip			
Automatic Shut off?	YES	YES	Identical
Patient Override Control?	YES	YES	Identical
Indicator Display: On/Off Status?	YES	YES	Identical
Low Battery?	N/A	N/A	Identical
Voltage/Current Level?	YES	YES	Identical
Timer Range (minutes)	45 Minutes – For Classic Mode 15 Minutes – For Flex+ mode	1 – 60 Minutes In step of 1 minute	**Modified** The modified device has prefixed treatment time of: 15 minutes and 45 minutes
Compliance with Voluntary Standards?	YES IEC 60601-1, IEC 60601-1-2, IEC60601-2-10, & ISO14971	YES IEC 60601-1, IEC 60601-1-2, IEC60601-2-10, & ISO14971	Identical
Compliance With 21 CFR 898	YES, the electrode cable can never be plugged in the AC socket, not even accidentally	YES, the electrode cable can never be plugged in the AC socket, not even accidentally	Identical
Weight	32.66 Kgs	32.66 Kgs	Identical
Dimension (L X B X H)	14”(L) X 17.5” (W) X 40”(H)	14”(L) X 17.5” (W) X 40”(H)	Identical
Housing Material and construction	ABS Plastic Body	ABS Plastic Body	Identical
Operating Temperature	Temperature: +15°C to +35°C Relative Humidity: 30 % to 75 % (non-condensing) Barometric pressure: 700 hPa to 1060 hPa	Temperature: +15°C to +35°C Relative Humidity: 30 % to 75 % (non-condensing) Barometric pressure: 700 hPa to 1060 hPa	Identical
Transport and storage environment	Temperature: +5°C to +45°C	Temperature: +5°C to +45°C	Identical

Device Features	Modified device	Predicate Device	Comparison
	Relative Humidity: 10% to 85% (non-condensing)	Relative Humidity: 10% to 85% (non-condensing)	

Comparison of output specification

Mode: Prep

S.No.	Parameters	MODIFIED DEVICE truSculpt flex	PREDICATE DEVICE Torc Body (K192039)
	Mode Name	Prep	Classic Vector
1.	**Waveform**	Symmetrical Biphasic	Symmetrical Biphasic
2.	**Shape**	Step Sine Wave	Step Sine Wave
3.	**Maximum Output Voltage**	100 Vpp @ 500Ω (± 10%) 125 Vpp @ 2KΩ (± 10%) 133 Vpp @ 10KΩ (± 10%)	51.6 Vpp @ 500Ω (± 10%) 62.4 Vpp @ 2KΩ (± 10%) 66 Vpp @ 10KΩ (± 10%)
4.	**Maximum Output Current**	200 mA @ 500 Ohm 62.5 mA @ 2K Ohm 13 mA @ 10K Ohm	103.2mA @ 500 Ohm 31.2 mA @ 2K Ohm 6.6 mA @ 10K Ohm
5.	**Pulse Width**	125 µS (± 10%) @500	124.7 µS (± 10%) @500
6.	**Frequency**	Channel1: 4000 Hz (± 10%) @500Ω Channel 2: 4001 – 4100 Hz (± 10%) @500Ω Resultant: 1 – 100 Hz	Channel1: 4000 Hz (± 10%) @500Ω Channel 2: 4001 – 4100 Hz (± 10%) @500Ω Resultant: 1 – 100 Hz
7.	**For Interferential modes only:** - **Beat frequency**	1 – 100 Hz	1 – 100 Hz
8.	**For multiphasic Waveform** **- Symmetrical Phases?** **- Phase duration**	 Yes 125 µS	 Yes 124.7 µS
9.	**Net charge**	0 µC @500Ω (Being Biphasic in nature the net charge would be Zero)	0 µC @500Ω (Being Biphasic in nature the net charge would be Zero)
10.	**Maximum Phase Charge**	12.5 µC	6.45 µC
11.	**Maximum Current Density**	2.88 mA/cm^2 *measured with 59 x 59 9mm square electrodes	1.15 mA/cm^2 *measured with 50 x 90mm rectangular electrodes
12.	**Maximum Power Density**	0.144 Watt/cm^2 *measured with 59 x 59mm square electrodes	0.0295 Watt/cm^2 *measured with 50 x 90mm rectangular electrodes
13.	**Burst Mode** - **Pulses Per Burst**	N/A	N/A

S.No.	Parameters	MODIFIED DEVICE truSculpt flex	PREDICATE DEVICE Torc Body (K192039)
	- **Burst Per second** - **Burst Duration** - **Duty Cycle**		
14.	**ON Time**	N/A	N/A
15.	**OFF Time**	N/A	N/A
16.	**Additional Features**	Sweep Frequency 1- 100 Hz	Sweep Frequency 1- 100 Hz

Mode: Tone

S.No.	Parameters	MODIFIED DEVICE truSculpt flex	PREDICATE DEVICE Torc Body (K192039)
	Output Waveform	Tone	Power Sequence
1.	**Waveform**	Symmetrical Biphasic	Symmetrical Biphasic
2.	**Shape**	Square wave	Square Wave
3.	**Maximum Output Voltage**	70 Vpp @ 500Ω (± 10%) 125 Vpp @ 2KΩ (± 10%) 150 Vpp @ 10KΩ (± 10%)	51 Vpp @ 500Ω (± 10%) 63 Vpp @ 2KΩ (± 10%) 66 Vpp @ 10KΩ (± 10%)
4.	**Maximum Output Current**	140 mA@ 500 Ohm 62.5 mA @ 2K Ohm 15 mA @ 10K Ohm	102 mA @ 500 Ohm 31.5 mA @ 2K Ohm 6.6 mA @ 10K Ohm
5.	**Pulse Width**	350 μS (± 10%) @ 500Ω	350 μS (± 10%)
6.	**Frequency**	99 Hz (± 10%) @ 500Ω	99 Hz (± 10%)
7.	**Beat frequency**	N/A	N/A
8.	**For multiphasic Waveform** **Symmetrical Phases?** **Phase duration**	Yes, Symmetrical Biphasic 350 μS (± 10%)	Yes, Symmetrical Biphasic 350 μS (± 10%)
9.	**Net charge**	0 μC @500Ω (Being Biphasic in nature the net charge would be Zero)	0 μC @500Ω (Being Biphasic in nature the net charge would be Zero)
10.	**Maximum Phase Charge**	24.50 μC @ 500 Ω Load	17.85 μC @ 500 Ω Load
11.	**Maximum Current density**	2.02 mA/cm2 *measured with 59 x 59 mm square electrodes	1.14 mA/cm^2 *measured with 50 x 90mm rectangular electrodes
12.	**Maximum Power Density**	0.070 Watts/cm_2 *measured with 59 x 59 mm square electrodes	0.029584 Watt/cm^2 *measured with 50 x 90mm rectangular electrodes
13.	**Burst Mode** - **Pulses Per Burst** - **Burst Per second** - **Burst Duration** **Duty Cycle**	N/A	N/A
14.	**ON Time**	6 seconds	6 seconds
15.	**OFF Time**	4 seconds	4 seconds
13	**Additional Features**	-	-

Mode: Sculpt

S.No.	Parameters	MODIFIED DEVICE truSculpt flex	PREDICATE DEVICE Torc Body (K192039)
	Output Waveform	Sculpt	Dynamic Rotation
1.	**Waveform**	Symmetrical Biphasic	Symmetrical Biphasic
2.	**Shape**	Modulated Sine Wave	Modulated Sine Wave
3.	**Maximum Output Voltage**	100 Vpp @ 500Ω (± 10%) 125 Vpp @ 2KΩ (± 10%) 135 Vpp @ 10KΩ (± 10%)	51.2 Vpp @ 500Ω (± 10%) 63.2 Vpp @ 2KΩ (± 10%) 66 Vpp @ 10KΩ (± 10%)
4.	**Maximum Output Current**	200 mA @ 500 Ohm 62.5 mA @ 2K Ohm 13.5 mA @ 10K Ohm	102.4 mA @ 500 Ohm 31.6 mA @ 2K Ohm 6.56 mA @ 10K Ohm
5.	**Pulse Width**	125 μS (± 10%) @ 500Ω	124.9 μS (± 10%) @ 500Ω
6.	**Frequency**	4000 Hz (± 10%) @ 500Ω Resultant: 1 – 100 Hz	4002 Hz (± 10%) @ 500Ω Resultant: 1 – 100 Hz
7.	**Beat frequency**	N/A	N/A
8.	**For multiphasic Waveform Symmetrical Phases?** **Phase duration**	Yes, Symmetrical Biphasic 125 μS (± 10%)	Yes, Symmetrical Biphasic 124.9 μS (± 10%)
9.	**Net charge**	0 μC @500Ω (Being Biphasic in nature the net charge would be Zero)	0 μC @500Ω (Being Biphasic in nature the net charge would be Zero)
10.	**Maximum Phase Charge**	12. 5 μC	6.4 μC
11A.	**Maximum Current density**	2.88 mA/cm^2 *measured with 59 x 59 9mm square electrodes	1.14 mA/cm^2 *measured with 50 x 90mm rectangular electrodes
12A.	**Maximum Power Density**	0.144 Watt/cm^2 *measured with 59 x 59mm square electrodes	0.0291 Watts/cm^2
13.	**Burst Mode** - **Pulses Per Burst** - **Burst Per second** - **Burst Duration Duty Cycle**	N/A	N/A
14.	**ON Time**	N/A	N/A
15.	**OFF Time**	N/A	N/A
13	**Additional Features**	Sweep Frequency 1- 100 Hz	Sweep Frequency 1- 100 Hz

There are no changes to the indications for use, fundamental scientific principles, performance specifications, or operation of the device. Although there are minor differences observed between the individual mode parameters of truSculpt flex and the predicate device, no differences found raised any questions regarding the safety and effectiveness of the modified device as the observed deviation in values is within the limits as per "Guidance Document for Powered Muscle Stimulator 510(k)s", issued on June 9, 1999, ANSI/AAMI NS4:2013 (R2017) standard for electrical stimulators.

The fundamental scientific technology is not changed in the modified device, and the changes are solely considered for ease of use for the clinician. The truSculpt flex generates the same stimulation to contract the muscles rhythmically to achieve the intended use of strengthening, firming, and toning the muscles of the abdomen, thighs, and buttocks. The clinician can increase or decrease the intensity as per the desired stimulation.

Non-clinical Testing

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the previously cleared Torc Body device. The truSculpt flex device met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared device. No new safety or performance issues were raised during testing.

Non-clinical Bench Testing:

- Reliability Testing
- Compliance Testing (IEC60601-1, IEC60601-1-2)
- Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)
- Quality System Regulation (21CFR820)
- Application of usability engineering to medical devices (IEC 62366)
- Application of risk management to medical devices (ISO 14971)
- Symbols to be used with medical device labels, labelling and information to be supplied (ISO 15233)
- Biological evaluation of medical devices (ISO 10993-1)

CONCLUSION

The information and testing presented in this traditional 510(k) demonstrate that the truSculpt flex device performs as designed and intended, and is substantially equivalent to the predicate device (K192039). The changes made do not affect the safety and effectiveness of the device.