March 29, 2020

Johari Digital Healthcare Limited
Pooja Johari
Founder and Director Marketing
G-582, 584 EPIP, Boranada
Jodhpur, Rajsthan 342008 India

Re: K192039
Trade/Device Name: Torc Body
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 24, 2019
Received: December 30, 2019

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,

For Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192039

Device Name
Torc Body

Indications for Use *(Describe)*
Torc Body is indicated to be used for:

- Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.
- Strengthening, toning and firming of buttocks & 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
As required by 21 CFR 807.92(c)

Device Name	Torc Body
Submitters name/ contact details	Nisha Johari Johari Digital Healthcare Ltd G-582, 584 EPIP, Boranada, Jodhpur – India – 342008 Contact number: + 1 - 888-412-3160
Summary Preparation Date	20-Mar-2020
Device Trade Name	Torc Body
Device / Proprietary Name	Torc Body
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	K131291
Address and Registration	Johari Digital Healthcare Ltd G-582, 584 EPIP, Boranada, Jodhpur – India – 342008
Contact Person:	Nisha Johari
Contact Number:	+91-9829954228
FDA Registration	8040537

Device Description

Torc Body, the Powered Muscle Stimulator, is intended to improve tone and strengthen the muscles of the abdomen, buttocks, and thighs and to firm the abdomen muscles.

The modified Torc Body, as described in this submission, is an upgrade from its previous version; which includes User- Friendly GUI, Internal power supply, and a wheeled console allowing clinicians to navigate and operate the device effortlessly. We intend to market this device to clinicians, as a prescription device. For ease of use and operation for the clinicians, we have 3 modes (suggestive):

- CLASSIC VECTOR is only necessary for non-active patients. It creates a twisting motion to warm up, build blood circulation and slowly build a tolerance to muscle contractions.
- POWER SEQUENCE contracts the muscles, holds it and then relaxes it to increase strength and muscle endurance.
- DYNAMIC ROTATION - Fast, sequential contractions of the muscles which leads to toning and firming.

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 Torc Body, complete care and considerable measures have been taken to retain its safety and effectiveness. Torc Body device complies with voluntary standards.

Intended Use

Torc Body is indicated to be used for:

- Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.

- Strengthening, toning and firming of buttocks & thighs.

The device safety and efficacy was demonstrated by performance data and 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 , K131291). The modification made to the device include:

- User Friendly GUI- LCD with wide angle view that significantly facilitates the use of the device.
- Power Supply- Internal power supply in place of external AC/DC adaptor and rechargeable battery. Wheeled Console- Allows clinicians to navigate and operate the device effortlessly
- Prescriptive device- we intend to market this device to clinicians, we propose making it a prescription device.

Comparison of Technological Characteristics

A comparison below 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	**K192039**	K131291	N/A
Device Name, Model	Torc Body	Torc Body	**Design revision updated to V2.0**
Manufactured For	7E LLC	7E LLC	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	OTC	**Modified;** **We intend to market this device to clinicians and propose making it a prescription device.**
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	AC/DC Adaptor & 24V DC Ni MH Rechargeable Battery	**Modified;** **The modified device uses an internal medical grade**

			power supply, in place of AC/DC adaptor and rechargeable battery used in the predicate device. The internal power supply complies with all necessary voluntary standards.
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 in between device and patient	(a) AC Power supply is converted to DC Power supply through Adaptor, which uses a transformer in between the Low and High voltage sides. Hence there is insulation of mains from Circuitry. (b) The device operates on Ni-Mh rechargeable battery	**Modified;** **The new version of Torc Body has 2XMOPP level isolation as required by the IEC standards.**
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 self adhesive electrodes , 4 electrode lead wires, , 1 AC Power Cord	Main unit, 8 electrodes, 4 electrode lead wires, 6 elastic belts (2 large, 2 medium, 2 small), 1 AC Adapter.	**Modified;** **The modified device has an internal medical grade power supply with an AC power cord; the predicate device has a rechargeable battery with an AC adapter.**
Display	12” LCD	5.7” LCD	**Modified;**

			Modified for better visual which gives a wide view angle.
Number of Output Modes	03 (Classic Vector, Power Sequence, Dynamic Rotation)	03 (ABS, BTS, CVL)	**Modified;** **Name of the modes (Classic Vector, Power Sequence, Dynamic Rotation) has been modified for a clear understanding of the clinician.**
Number of Output Channels Synchronous or Alternating?	2 (Two) Synchronous (a) Output 1 to 2 are completely isolated. Only power supply and ground are common	2 (Two) Synchronous (a) Output 1 to 2 are completely isolated. Only power supply and ground are common	Identical
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 Trip	NO	NO	Identical
Automatic Shut off?	YES	YES	Identical
Patient Override Control?	YES	YES	Identical
Indicator Display: On/Off Status?	YES	YES	Identical
Low Battery?	N/A	YES	**Modifed;** **The modified device does not have a battery and, therefore, does not have**

			a battery indicator display.
Voltage/Current Level?	YES	YES	Identical
Timer Range (minutes)	1 – 60 Minutes In step of 1 minute	1 – 60 Minutes In step of 1 minute	Identical
Compliance with Voluntary Standards?	YES IEC 60601-1, IEC 60601-1-2,IEC60601-2-10, and ISO14971	YES IEC 60601-1, IEC 60601-1-2,IEC60601-2-10, and 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	3.0 KG	**Modified;** **The modified device has been upgraded to a wheeled console.**
Dimension (L X B X H)	14”(L) X 17.5” (W) X 40”(H)	8.2”(L) x 6.0” (W) x 4.0” (H)	**Modified;** **The modified device has been upgraded to a wheeled console.**
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 Relative Humidity: 10% to 85% (non-condensing)	Temperature: +5°C to +45°C Relative Humidity: 10% to 85% (non-condensing)	Identical

Output Specification – Comparion with Predicate Devcies

Mode: Classic Vector

Characteristics	**MODIFIED DEVICE** Torc Body (K192039)	**PREDICATE DEVICE** Torc Body (K131291)	**Comparison**
Output Waveform	Classic Vector	ABS-6	N/A
Waveform	Symmetrical Biphasic	Symmetrical Biphasic	Identical
Shape	Step Sine Wave	Square Wave	**Modified;** **The modified devices uses sinewave**
Maximum Output Voltage	51.6 Vpp @ 500Ω (± 10%) 62.4 Vpp @ 2KΩ (± 10%) 66 Vpp @ 10KΩ (± 10%)	51 Vpp @ 500Ω (± 10%) 63 Vpp @ 2KΩ (± 10%) 66 Vpp @ 10KΩ (± 10%)	**Modified;** **The difference between the two devices at 500Ω and 2KΩ values, is negligible.**
Maximum Output Current	103.2 mA pp @ 500 Ohm 31.2 mA pp @ 2K Ohm 6.6 mA pp @ 10K Ohm	102 mA pp @ 500 Ohm 31.5 mA pp @ 2K Ohm 6.6 mA pp @ 10K Ohm	**Modified;** **The difference between the two devices at 500Ω and 2KΩ values, is negligible.**
Pulse Width	124.7 μS (± 10%) @500Ω	350 μS (± 10%)	**Modified;** **The pulse width is less than the predicate device, however the waveshape is sinewave with duty cycle of 50%, which implies that the strength of the stimulation is essentially the**

			same in both devices.
Frequency	4010 Hz (± 10%) @500Ω Resultant: 1 – 100 Hz	99 Hz (± 10%)	**Modified;** **The pulse rate is higher in the modified device, but due to the interferential effect the resultant frequency is only 1 – 100 Hz (sweeping), which is virtually identical to the predicate devcie with frequency (99 Hz).**
For Interferential modes only: -Beat frequency	N/A	N/A	Identical
For multiphasic Waveform - Symmetrical Phases? - Phase duration	Yes 124.7 μS	Yes 350 μS	Identical **Modified;** **The phase duration is less than the predicate device, however the waveshape is sinewave with duty cycle of 50%, which implies that the strength of the stimulation is essentially the same in both devices.**
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)	Identical
Maximum Phase Charge	6.435 μC	35.7 μC	**Modified;**

			The phase charge is less than the predicate device, however the waveshape is sinewave with duty cycle of 50%, which implies that the strength of the stimulation is essentially the same in both devices.
Maximum Current Density	1.15 mA/cm^2 *measured with 50 x 90mm rectangular electrodes	1.14 mA/cm^2 *measured with 50 x 90mm rectangular electrodes	**Modified;** **The difference between the values of both devices is negligible.**
Maximum Power Density	0.0295 Watt/cm^2 *measured with 50 x 90mm rectangular electrodes	0.0289 Watt/cm^2 *measured with 50 x 90mm rectangular electrodes	**Modified;** **The difference between the values of both devices is negligible.**
Burst Mode -Pulses Per Burst -Burst Per second -Burst Duration -Duty Cycle	N/A	N/A	Identical
ON Time	N/A	5.5 seconds	**Modified;** **Modified device does not have ON time.**
OFF Time	N/A	5.5 seconds	**Modified;** **Modified device does not have OFF time.**
Additional Features	Sweep Frequency 1-100 Hz	N/A	**The modified device has feature of sweep frequency.**

Mode: Power Sequence

Characteristics	MODIFIED DEVICE Torc Body (**K192039)**	PREDICATE DEVICE Torc Body (K131291)	Comparison
Output Waveform	Power Sequence	ABS-6	N/A
Waveform	Symmetrical Biphasic	Symmetrical Biphasic	Identical
Shape	Square wave	Square Wave	Identical
Maximum Output Voltage	50.8 Vpp @ 500Ω (± 10%) 64 Vpp @ 2KΩ (± 10%) 65.6 Vpp @ 10KΩ (± 10%)	51 Vpp @ 500Ω (± 10%) 63 Vpp @ 2KΩ (± 10%) 66 Vpp @ 10KΩ (± 10%)	**Modified;** **The difference between the values of both devices at different is negligible.**
Maximum Output Current	101.6 mA pp @ 500 Ohm 32 mA pp @ 2K Ohm 6.56 mA pp @ 10K Ohm	102 mA pp @ 500 Ohm 31.5 mA pp @ 2K Ohm 6.6 mA pp @ 10K Ohm	**Modified;** **The difference between the values of both devices is negligible.**
Pulse Width	350 μS (± 10%) @ 500Ω	350 μS (± 10%)	Identical
Frequency	99.91 Hz (± 10%) @ 500Ω	99 Hz (± 10%)	**Modified;** **The difference between the values of both devices is negligible.**
Beat frequency	N/A	N/A	Identical
For multiphasic Waveform Symmetrical Phases? Phase duration	Yes, Symmetrical Biphasic 350 μS (± 10%)	Yes, Symmetrical Biphasic 350 μS (± 10%)	Identical
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)	Identical
Maximum Phase Charge	35.56 μC @ 500 Ω Load	35.7 μC @ 500 Ω Load	**Modified;**

			The difference between the values of both devices is negligible.
Maximum Current density	1.13 mA/cm^2 *measured with 50 x 90mm rectangular electrodes	1.14 mA/cm^2 *measured with 50 x 90mm rectangular electrodes	**Modified;** **The difference between the values of both devices is negligible.**
Maximum Power Density	0.0287 Watt/cm^2 *measured with 50 x 90mm rectangular electrodes	0.0289 Watt/cm^2 *measured with 50 x 90mm rectangular electrodes	**Modified;** **The difference between the values of both devices is negligible.**
Burst Mode -Pulses Per Burst -Burst Per second -Burst Duration -Duty Cycle	N/A	N/A	Identical
ON Time	6 seconds	5.5 seconds	**Modified;** **The difference between the values of both devices is virtually identical.**
OFF Time	4 seconds	5.5 seconds	**Modified;** **The difference between the values of both devices is virtually identical.**
Additional Features	-	-	Identical

Mode: Dynamic Rotation

Characteristics	**MODIFIED DEVICE** Torc Body (**K192039)**	**PREDICATE DEVICE** Torc Body (K131291)	**Comparison**
Output Waveform	Dynamic Rotation	ABS-6	N/A
Waveform	Symmetrical Biphasic	Symmetrical Biphasic	Identical

Shape	Modulated Sine Wave	Square Wave	**Modified;** **The modified devices uses modulated sinewave.**
Maximum Output Voltage	51.2 Vpp @ 500Ω (± 10%) 63.2 Vpp @ 2KΩ (± 10%) 65.6 Vpp @ 10KΩ (± 10%)	51 Vpp @ 500Ω (± 10%) 63 Vpp @ 2KΩ (± 10%) 66 Vpp @ 10KΩ (± 10%)	**Modified;** **The difference between the two devices values at different load values is negligible.**
Maximum Output Current	102.4 mA pp @ 500 Ohm 31.6 mA pp @ 2K Ohm 6.56 mA pp @ 10K Ohm	102 mA pp @ 500 Ohm 31.5 mA pp @ 2K Ohm 6.6 mA pp @ 10K Ohm	**Modified;** **The difference between the two devices values at different load values is negligible**
Pulse Width	124.9 μS (± 10%) @ 500Ω	350 μS (± 10%)	**Modified;** **The pulse width is less than the predicate device, however the waveshape is sinewave with duty cycle of 50%, which implies that the strength of the stimulation is essentially the same in both devices.**
Frequency	4002 Hz (± 10%) @ 500Ω Resultant: 1 – 100 Hz	99 Hz (± 10%)	**Modified;** **The pulse rate is higher in the modified device, but due to the interferential effect the resultant frequency is only**

			1 – 100 Hz (sweeping), which is virtually identical to the predicate devcie with frequency (99 Hz).
Beat frequency	NA	NA	Identical
For multiphasic Waveform Symmetrical Phases? Phase duration	Yes, Symmetrical Biphasic 124.9 μS (± 10%)	Yes, Symmetrical Biphasic 350 μS (± 10%)	Identical **Modified;** **The phase duration is less than the predicate device, however the waveshape is sinewave with duty cycle of 50%, which implies that the strength of the stimulation is essentially the same in both devices.**
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)	Identical
Maximum Phase Charge	6.4 μC	35.7 μC	**Modified;** **The phase charge is less than the predicate device, however the waveshape is sinewave with duty cycle of 50%, which implies that the strength of the stimulation is essentially the same in both devices.**

Maximum Current density	1.14 mA/cm^2 *measured with 50 x 90mm rectangular electrodes	1.14 mA/cm^2 *measured with 50 x 90mm rectangular electrodes	**Modified;** **The difference between the values of both devices is negligible.**
Maximum Power Density	0.0291 Watts/cm^2 *measured with 50 x 90mm rectangular electrodes	0.0289 Watts/cm^2 *measured with 50 x 90mm rectangular electrodes	**Modified;** **The difference between the values of both devices is negligible.**
Burst Mode -Pulses Per Burst -Burst Per second -Burst Duration -Duty Cycle	NA	NA	Identical
ON Time	NA	5.5 seconds	**Modified;** **Modified device does not have ON time.**
OFF Time	NA	5.5 seconds	**Modified;** **Modified device does not have OFF time.**
Additional Features	Sweep Frequency 1-100 Hz	-	**The modified device has feature of sweep frequency.**

Although there are minor differnces observed between the individual mode parameters of modified Torc Body and the predicate device, no difference found raised any questions regarding safety and effectiveness of the modified device. The primary change from the predicate Torc Body device to Torc Body Version 2.0 is that the new device model provides an internal power supply instead of a rechargeable battery; a user-friendly GUI; and a wheeled console. We are also proposing to change the type of use from Over the Counter to Prescription.

There are no changes to the indications for use, fundamental scientific principles, performance specifications, or operation of the device.

User-Friendly GUI: The modified Torc Body device has a larger touch screen LCD, which gives a wide-angle view that significantly facilitates the use of the device.

Power Supply: The modified Torc Body device is equipped with an internal medical grade power supply, instead of an AC/DC adaptor and rechargeable battery (predicate device). Testing under voluntary standards has been carried out to make sure the power supply is safe and there are no new risks with this change.

Wheeled Console: The Torc Body has been upgraded to a modern, sleek, wheeled console which allows clinicians to navigate and operate the device effortlessly.

Prescription Device: As a manufacturer, we understand that the modified Torc Body device is based on the same technology and intended for the same use as its predicate device and that the modifications will not affect safety and effectiveness. However, as we intend to market this device to clinicians, we propose making it a prescription device.

The fundamental scientific technology is not changed in the modified device, and the change is solely considered for ease of use to the clinician. 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 Torc Body, complete care and considerable measures have been taken to retain its safety and effectiveness. The modified Torc Body device complies with voluntary standards, hence the modified device is substantially equivalent to the predicate device.

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 modified device Torc Body 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 modified Torc Body device performs as designed and intended, and is substantially equivalent to the predicate device (K131291). The changes made do not affect the safety and effectiveness of the device.