July 21, 2024

Zimmer MedizinSysteme GmbH
Scott Blood
Principal Regulatory Consultant
QARA Consulting LLC
151 Gleasondale Road
Stow, MA 01775 USA

Re: K240347
Trade/Device Name: PTG-05
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 20, 2024
Received: June 24, 2024

Dear Scott Blood:

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.

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K240347

Device Name

PTG-05

Indications for Use *(Describe)*

• Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.
• Strengthening, toning, and firming of buttocks & thighs.
• Strengthening, toning, and firming of arms.

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
PTG-05
K240347

1. **Basic Information-Submitter**:

510(k) Owner:	Zimmer MedizinSysteme GmbH Junkersstrasse 9 89231 Neu-Ulm Germany Establishment Registration: 8010720
	Ms. Ute Killet Manager Regulatory Affairs Phone: +49-7319761-216 Fax: +49-731-9761-118 E-Mail: u.killet@zimmer.de
Official Contact:	Mr. Scott Blood Principal Regulatory Consultant Phone: 978.729.5978 Fax: +49-731-9761-118 E-mail: scottqara@gmail.com
Date Summary Prepared:	February 22, 2024

2. **Device Name**:

Trade Name:	PTG-05
Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation Number:	21 CFR 890.5850
Product Code:	NGX
Classification:	Class II

3. **Predicate Device**: truSculpt Flex – K212866
   Company Name: Johari Digital Healthcare Limited

4. **Device Description**:

The PTG-05 is a non-invasive therapeutic device. The device produces an electrical current that interacts with the tissues of the human body. The PTG-05 is intended to increase the musculature of the abdominals, buttocks, arms and thighs. The device is intended to be used with single-use electrodes from Zimmer MedizinSysteme GmbH (K140340) or equivalent. The output of biphasic and middle frequency currents for muscle stimulation

with maximum 8 channels at a time allows to treat several treatment areas simultaneously.

For an efficient treatment the user is guided via user interface throughout the whole treatment. First, the user can select the treatment area with the device illustrating where to place the electrodes. The modules are automatically matched to the specific treatment area while highlighted in the color of the matching trunk cable of the module.

In the therapy screen, the user can select one of the 5 pre-set treatment protocols for each treatment region based on the training level of the patient.
During the treatment, an animation of the electrodes is shown in the screen that outlines if the protocol is in a "work-phase" which means a contraction phase or if the protocol is in a "relax-phase" which refers to a muscle relax phase.

Expert mode
In addition, all 4 modules can be split into 8 channels using "Expert mode" for a precise adjustment of the individual channels. This is ideal to set different intensities for the inner musculature than for the outer musculature of a specific treatment area, for example.

Link-mode
All of the modules can be linked together which enables the use of the remote control where the patient by itself can set the intensity and stop the therapy at any time.

5. Indications for Use Statement:

The PTG-05 is intended for:

- Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.
- Strengthening, toning and firming of buttocks & thighs.
- Strengthening, toning and firming of arms

The Indications for Use statement of PTG-05 is similar to that of the predicate device NuEra Tight RF Family.

6. **Technological Characteristics**:

There are only a few technological differences between the subject device and the predicate device. Those differences are discussed below and do not affect or raise any new types of safety or performance questions.

TECHNOLOGICAL CHARACTERISTICS	SUBJECT DEVICE Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	PREDICATE DEVICE Johari Digital Healthcare Limited truSculpt flex **K212866**	Equivalence Discussion
Power Source	100-240VAC, 50/60Hz, max. 100VA	100-240AC, 50/60Hz, 75VA	Similar
Method of Line Current Isolation	a) AC Power supply is converted to DC Power supply thorough a medical grade PSU, which has isolation of 2XMOPP (IEC 60601-1) (b) Isolation thru transformer between device and patient	a) AC Power supply is converted to DC Power supply thorough a medical grade PSU, which has isolation of 2XMOPP (IEC60601-1) (b) Isolation thru transformer between device and patient	Identical
Patient Leakage Current Normal condition	Normal condition = less than 100µA	Normal condition = less than 100µA	Identical
Patient Leakage Current Single Fault condition	Single fault condition = less than 300 µA	Single fault condition = less than 300 µA	Identical
Components	Main unit, 8 reusable trunk cables 16 reusable electrode cables 2 packages of single-use Zimmer electrodes (K140340) 1 Power Cord	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)	Similar The components are sufficient for the device operation, so there are no questions of safety or effectiveness. The predicate device supports 4 output channels which allow the connection of 16 electrodes to the devices whereby 2 electrodes are always run in parallel. The subject device has 8 output channels suitable to also attach 16 electrodes. This configuration offers an even safer usage of the device while the application form remains the same and the treatment is as effective as the predicate device.
Display	12'' LCD	12" LCD	Identical
Number of Output Modes	5 Level 1, Level 2, Level 3, Level 4, Level Intense	3 Prep, Tone, Sculpt	Similar The output modes of the subject device are precisely matched to the body regions. The predicate device does not have this feature. The output modes of the predicate device are identical for all body regions. Therefore, the subject device is safer due to the adjustment to the body region. The predicate device offers 3 output

TECHNOLOGICAL CHARACTERISTICS		SUBJECT DEVICE Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	PREDICATE DEVICE Johari Digital Healthcare Limited truSculpt flex **K212866**	Equivalence Discussion
				modes while the subject device offers 5 output modes thereby output mode 1
Output Channels	Number of Output Channels	8	4	Similar The number of outputs is being increased from 4 to 8 to provide enhanced customization and flexibility to the user. The predicate device supports 4 output channels which allow the connection of 16 electrodes to the devices whereby 2 electrodes are always run in parallel. The subject device has 8 output channels suitable to attach 16 electrodes. This configuration offers even safer usage of the device while the application form remains the same and the treatment is as effective as the predicate device.
	Synchronous or Alternating?	Synchronous	Synchronous	Identical
Method of Channel Isolation		Output 1 to 8 are completely isolated by transformers. Only power supply and ground are common.	Transformer	Identical
Regulated Current Or Regulated Voltage		Regulated current	Tran conductance	Different The subject device controls the output current by a common current regulation method this ensures safety of the device and is tested during IEC 60601-2-10 testing.
Software/Firmware/ Microprocessors controls?		Yes	Yes	Identical
Automatic Overload Trip?		Yes	Yes	Identical
Automatic No-Load Trip?		Yes	No	Different Device studied for electrical safety in its intended environment per IEC 60601-1 and determined to be electrical safe.
Automatic Shut off?		Yes (In case of therapy time running out or in case of an error)	Yes	Identical
Patient Override Control?		Yes (If override control means that the patient can stop the treatment.	Yes	Identical

TECHNOLOGICAL CHARACTERISTICS	SUBJECT DEVICE Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	PREDICATE DEVICE Johari Digital Healthcare Limited truSculpt flex **K212866**	Equivalence Discussion
	He can do so by pressing pause on the remote)		
On/Off Status on Display	Yes	Yes	Identical
Low Battery on Display	N/A	N/A	Identical
Voltage/Current Level on Display	Yes	Yes	Identical
Timer Range (minutes)	Up to max. 30 minutes per protocol	45 Minutes – for Classic Mode 15 Minutes – for Flex+ mode	Similar Treatment time is in the range of the predicate device and is a user-settable parameter.
Compliance With Voluntary Standards?	Yes IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 & ISO 14971	Yes IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 & ISO 14971	Identical
Compliance With 21 CFR 898?	Yes, the electrode cable can never be plugged in the AC socket, not even accidentally as the cable has an isolation on both sides.	Yes, the electrode cable can never be plugged in the AC socket, not even accidentally	Identical
Weight	45kg (inlcuding max. work load)	32.66 Kgs	Different The weight relates to the technical setup and therefore differs but does not influence safety.
Dimension (L x W x H)	117cm x 80cm x 80cm 31”(L) x 31”(W) x 46” (H)	14“(L) x 17.5“(W) x 40“(H)	Different The dimensions of the predicate device are verified and validated during safety and usability testing. Both tests show that the dimensions are adequate and guarantee a safe and effective usage of the device.
Housing Material and construction	PC-ABS Plastic Body	ABS Plastic Body	Similar Changing the material of the subject device to PC-ABS does not effect safety as mechanical properties of the 2 materials are equal and material behavior for the subject device is also tested while IEC60601-1 test.
Operating Temperature	50°F to 104° (+10°C to + 40°C) 10% to 90% rel. humidity, 620–1060 hPa	Temperature: +15°C to +35°C Relative Humidity: 30% to 75% (non-condensing) Barometric pressure:	Different No influence on safety and effectiveness

TECHNOLOGICAL CHARACTERISTICS	SUBJECT DEVICE Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	PREDICATE DEVICE Johari Digital Healthcare Limited truSculpt flex **K212866**	Equivalence Discussion
		700hPA to 1060hPa	
Transport and storage environment	-4°F to 158°F (-20°C to + 70°C) 10% to 90% rel. humidity, 620–1060 hPa	Temperature: +5°C to 45°C Relative Humidity: 10% to 85% (non-condensing)	Different No influence on safety and effectiveness

Output Specification Comparison by Mode

#	Parameters	SUBJECT DEVICE Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	PREDICATE DEVICE Johari Digital Healthcare Limited truSculpt flex **K212866**
	Mode Name	Level 1 Level 2	Prep
1.	Waveform	Symmetrical Biphasic	Symmetrical Biphasic
2.	Shape	Rectangular Step Wave Square Wave (Biphasic rectangular symmetric)	Step Sine Wave
3.	Maximum Output Voltage	100 Vpp @ 500Ω 320 Vpp @ 2kΩ 360 Vpp @ 10kΩ 100Vpp @ 500Ω 320Vpp @2kΩ 360Vpp @10kΩ	100Vpp @ 500Ω (±10%) 125Vpp @ 2KΩ (±10%) 133Vpp @ 10KΩ (±10%)
4.	Maximum Output Current[1]	200mA @ 500 Ohm 160mA @ 2k Ohm 36 mA @ 10kOhm 200mA @500 Ohm 160mA @2k Ohm 36mA @ 10k Ohm	200mA @ 500 Ohm 62.5mA @ 2K Ohm 13.5mA @ 10K Ohm
5.	Pulse Width	125µs, 400µs 200 µs, 300µs	125µS (± 10%) @ 500Ω
6.	Frequency	Pulse Frequency: 2500Hz@ 500 Ω = (1/125) 8000Hz@ 500 Ω = (1/ 400) Modulation: 20-24 Hz@ 500 Ω	Channel 1: 4000Hz (± 10%) @ 500 Ω Channel 2: 4001 - 4100Hz (± 10%) @ 500 Ω Resultant: 1 – 100Hz

[1] Device has a warning system that alerts the user when the maximum current density exceeds 2mA/cm^2.

#	Parameters	SUBJECT DEVICE Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	PREDICATE DEVICE Johari Digital Healthcare Limited truSculpt flex **K212866**
7.	For Interferential modes only - Beat frequency	N/A	1 – 100Hz
8.	For multiphasic Waveform - Symmetrical Phases? - Phase duration	No multiphasic wave form. Either biphasic or modulated sine wave.	Yes 125µS
9.	Net charge	0µC @ 500Ω (Being Biphasic in nature the net charge would be Zero)	0µC @ 500Ω (Being Biphasic in nature the net charge would be Zero)
10.	Maximum Phase Charge	12.5 µC (125µs pulse) 40 µC (400µs pulse) 20µC @500 Ω Load (200 µs) 30µC @500 Ω Load (300 µs)	12.5 µC
11.	Maximum Current Density	4.06 mA/ cm² *measured with 56mm round electrodes 4.06 mA/ cm² *measured with 56mm round electrodes	2.88 mA/cm² *measured with 59 x 59mm square electrodes
12.	Maximum Power Density	0.203 W/cm² *measured with 56mm round electrodes 0.203 W/cm² *measured with 56mm round electrodes	0.144 W/cm² *measured with 59 x 59mm square electrodes
13.	Burst Mode - Pulses Per Burst - Burst Per second - Bust Duration - Duty Cycle	N/A	N/A
14.	ON Time	N/A	N/A
15.	OFF Time	N/A	N/A
16.	Additional Features	N/A	Sweep Frequency 1-100Hz

#	Parameters	**SUBJECT DEVICE** Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	**PREDICATE DEVICE** Johari Digital Healthcare Limited truSculpt flex **K212866**
	Mode Name	Level 3 Level 4	Tone
1.	Waveform	Symmetrical Biphasic	Symmetrical Biphasic
2.	Shape	Rectangular Step Wave Square Wave (Biphasic rectangular symmetric)	Square Wave
3.	Maximum Output Voltage	100 Vpp @ 500Ω 320 Vpp @ 2kΩ 360 Vpp @ 10kΩ 100Vpp @ 500Ω 320Vpp @2kΩ 360Vpp @10kΩ	70Vpp @ 500Ω (±10%) 125Vpp @ 2KΩ (±10%) 150Vpp @ 10KΩ (±10%)
4.	Maximum Output Current[2]	200mA @ 500 Ohm 160mA @ 2k Ohm 36 mA @ 10kOhm 200mA @500 Ohm 160mA @2k Ohm 36mA @ 10k Ohm	140mA @ 500 Ohm 62.5mA @ 2K Ohm 15mA @ 10K Ohm
5.	Pulse Width	125µs, 400µs 200 µs, 300µs	350µS (± 10%) @ 500Ω
6.	Frequency	Pulse Frequency: 2500Hz@ 500 Ω 8000Hz@ 500 Ω Modulation: 28-45 Hz@ 500 Ω	99 Hz (± 10%) @ 500Ω
7.	For Interferential modes only - Beat frequency	N/A	N/A
8.	For multiphasic Waveform - Symmetrical Phases? - Phase duration	No multiphasic wave form. Either biphasic or modulated sine wave.	Yes, Symmetrical Biphasic 350 µS
9.	Net charge	0µC @ 500Ω (Being Biphasic in nature the net charge would be Zero)	0µC @ 500Ω (Being Biphasic in nature the net charge would be Zero)
10.	Maximum Phase Charge	12.5 µC (125µs pulse) 40 µC (400µs pulse) 20µC @500 Ω Load (200 µs) 30µC @500 Ω Load (300 µs)	24.50 µC @ 500Ω Load
11.	Maximum Current Density	4.06 mA/ cm² *measured with 56mm round electrodes 4.06 mA/ cm² *measured with 56mm round electrodes	2.02 mA/cm² *measured with 59 x 59mm square electrodes

[2] Device has a warning system that alerts the user when the maximum current density exceeds 2mA/cm².

#	Parameters	**SUBJECT DEVICE** Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	**PREDICATE DEVICE** Johari Digital Healthcare Limited truSculpt flex **K212866**
12.	Maximum Power Density	0.203 W/cm² *measured with 56mm round electrodes 0.203 W/cm² *measured with 56mm round electrodes	0.070 W/cm² *measured with 59 x 59mm square electrodes
13.	Burst Mode - Pulses Per Burst - Burst Per second - Bust Duration - Duty Cycle	N/A	N/A
14.	ON Time	N/A	6 seconds
15.	OFF Time	N/A	4 seconds
16.	Additional Features	N/A	N/A

#	Parameters	**SUBJECT DEVICE** Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	**PREDICATE DEVICE** Johari Digital Healthcare Limited truSculpt flex **K212866**
	Mode Name	Level 5	Sculpt
1.	Waveform	Symmetrical Biphasic	Symmetrical Biphasic
2.	Shape	Rectangular Step Wave Square Wave (Biphasic rectangular symmetric)	Modulated Sine Wave
3.	Maximum Output Voltage	100 Vpp @ 500Ω 320 Vpp @ 2kΩ 360 Vpp @ 10kΩ 100Vpp @ 500Ω 320Vpp @2kΩ 360Vpp @10kΩ	100Vpp @ 500Ω (±10%) 125Vpp @ 2KΩ (±10%) 135Vpp @ 10KΩ (±10%)
4.	Maximum Output Current[3]	200mA @ 500 Ohm 160mA @ 2k Ohm 36 mA @ 10kOhm 200mA @500 Ohm 160mA @2k Ohm 36mA @ 10k Ohm	200mA @ 500 Ohm 62.5mA @ 2K Ohm 13.5mA @ 10K Ohm
5.	Pulse Width	125µs, 400µs 200 µs, 300µs	125µS (± 10%) @ 500Ω
6.	Frequency	Pulse Frequency: 2500Hz@ 500 Ω 8000Hz@ 500 Ω Modulation: 35-65 Hz@ 500 Ω	4000Hz (± 10%) @ 500 Ω Resultant: 1 – 100Hz
7.	For Interferential modes only - Beat frequency	N/A	N/A
8.	For multiphasic Waveform - Symmetrical Phases? - Phase duration	No multiphasic wave form. Either biphasic or modulated sine wave.	Yes, Symmetrical Biphasic 125µS (± 10%)
9.	Net charge	0µC @ 500Ω (Being Biphasic in nature the net charge would be Zero)	0µC @ 500Ω (Being Biphasic in nature the net charge would be Zero)
10.	Maximum Phase Charge	12.5 µC (125µs pulse) 40 µC (400µs pulse) 20µC @500 Ω Load (200 µs) 30µC @500 Ω Load (300 µs)	12.5 µC
11.	Maximum Current Density	4.06 mA/ cm² *measured with 56mm round electrodes 4.06 mA/ cm² *measured with 56mm round electrodes	2.88 mA/cm² *measured with 59 x 59mm square electrodes

[3] Device has a warning system that alerts the user when the maximum current density exceeds 2mA/cm².

#	Parameters	**SUBJECT DEVICE** Zimmer MedizinSysteme GmbH PTG-05 **This Submission**	**PREDICATE DEVICE** Johari Digital Healthcare Limited truSculpt flex **K212866**
12.	Maximum Power Density	0.203 W/cm² *measured with 56mm round electrodes 0.203 W/cm² *measured with 56mm round electrodes	0.144 W/cm² *measured with 59 x 59mm square electrodes
13.	Burst Mode - Pulses Per Burst - Burst Per second - Bust Duration - Duty Cycle	N/A	N/A
14.	ON Time	N/A	N/A
15.	OFF Time	N/A	N/A
16.	Additional Features	N/A	Sweep Frequency 1-100Hz

7. Performance data

The technological characteristics of the PTG-05 device has been verified based on assessments of electrical safety, performance testing, biocompatibility and usability.

The following testing has been conducted with satisfactory results:

- Usability & Risk Management: Usability and Risk Management assessments were done using worst-case assumptions to verify user interface, safety features and satisfactory performance.
- Electrostimulation waveform measurement
- Waveform tracing

The following consensus standards were used in the development of this device:

Standards	Standards Organization	Standards Title
60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	IEC	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
60601-1-2 Edition 4.1 2020-09	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
60601-1-6 Edition 3.1 2013-10	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
62304 Edition 1.1 2015-06	IEC	Medical devices software –software life cycle processes
62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	IEC	Medical devices – Part 1: Application of usability engineering to medical devices
14971 Third Edition 2019-12	ISO	Medical devices – Application of risk management to medical devices

All required performance tests were conducted and show substantial equivalence with the predicate device.

8. Conclusion:

Zimmer MedizinSysteme GmbH has demonstrated that the PTG-05 device is substantially equivalent to the predicate device.