November 24, 2023

PAJUNK GmbH Medizintechnologie
Christian Quass, Director Regulatory Affairs
Karl-Hall-Str. 1
Geisingen, 78187
Germany

Re: K230701
Trade/Device Name: Stim2Go
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZI, GZJ, HCC
Dated: March 14, 2023
Received: March 14, 2023

Dear Christian Quass:

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,

Jitendra V. Virani -S

CDR Jitendra Virani, MS, MBA
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

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)*
K230701

Device Name
Stim2Go

Indications for Use *(Describe)*
As a powered muscle stimulator (NMES) the Stim2Go is indicated for the following conditions:
• Relaxation of muscle spasm
• 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
As a transcutaneous electrical nerve stimulator (TENS) for pain relief the Stim2Go is indicated for the following conditions:
• Symptomatic relief and management of chronic (long-term), intractable pain
• Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain
As a biofeedback device the Stim2Go is indicated for the following condition:
• Muscle re-education purposes
As a functional neuromuscular stimulator, the Stim2Go is indicated for the following conditions:
• Helps to relearn voluntary motor functions of the extremities
The movement-based biofeedback can only be used for patients with an active range of motion (ROM) which is defined as the ability of volitional movement resulting in a change of the concerned limb inclination angle of at least 10 degrees.

Type of Use *(Select one or both, as applicable)*

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

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary as required by 21 CFR 807.92(c).**

**Date of Preparation: 2023-11-20**

# Document Control Number: K230701


**510(k) owner:**

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Establishment Registration Number:
**9611612**

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## Device Name and Classification

| | |
|---|---|
| Device Name: | **Stim2Go** |
| Regulation Name**:** | **Powered Muscle Stimulator** |
| Document Control Number: | **K230701** |
| Regulation Number | **21 CFR 890.5850** |
| Product Code: | **IPF** |
| Subsequent Product Codes | **GZI, GZJ, HCC** |
| Establishment Registration Number: | **9611612** |
| Regulatory Class: | **II** |
| Panel: | **Physical Medicine** |

## Predicate Device

| | |
|---|---|
| Device Name: | **STIWELL med4** |
| Manufacturer | **Otto Bock Healthcare Product GmbH** |
| Regulation Name**:** | **Powered Muscle Stimulator** |
| Document Clearance Number: | **K080950** |
| Regulation Reference**:** | **21 CFR 890.5850** |
| Product Code: | **IPF** |
| Subsequent Product Codes | **GZI, GZJ, HCC, KPI** |
| Establishment Registration Number: | **3005190268** |
| Regulatory Class: | **II** |
| Panel: | **Physical Medicine** |

## Narrative Device Description

The **Stim2Go** is a portable, hand-held / body-worn electrical stimulation device mainly for the treatment of neurological patients with motor and/or sensory impairments. **Stim2Go** offers transcutaneous electrical stimulation of peripheral nerves (motor and/or sensory).

Typically, **Stim2Go** is used to elicit muscle contractions (known as Neuro Muscular Electrical Stimulation (NMES)), to treat pain (known as Transcutaneous Electrical Nerve Stimulation (TENS)) or to be applied as Functional Electrical Stimulation (FES).

**Stim2Go** uses a built-in sensor to analyze the patient's movement data in real time. Based on the analysis result, pre-configured stimulation patterns can be triggered to achieve a specific, predetermined effect based on the patient's movements.

**Stim2Go** is intended for use in a clinical setting or when used by end users in home care, then necessarily with assistance. It is intended for use as an on-demand service - not permanently.

**Stim2Go** is controlled wirelessly by a smart device – the App is freely available in the Appstore. The App allows users to execute a variety of therapy programs and even to control parameters on a very detailed level. **Stim2Go** is tested and certified according to the international standards for medical electrical devices and systems.

**Indications for use**

As a powered muscle stimulator (NMES) the Stim2Go is indicated for the following conditions:

- Relaxation of muscle spasm
- 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

As a transcutaneous electrical nerve stimulator (TENS) for pain relief the Stim2Go is indicated for the following conditions:

- Symptomatic relief and management of chronic (long-term), intractable pain
- Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain

As a biofeedback device the Stim2Go is indicated for the following condition:

- Muscle re-education purposes

As a functional neuromuscular stimulator, the Stim2Go is indicated for the following conditions:

- Helps to relearn voluntary motor functions of the extremities

**The movement-based biofeedback can only be used for patients with an active range of motion (ROM) which is defined as the ability of volitional movement resulting in a change of the concerned limb inclination angle of at least 10 degrees.**

**Substantial Equivalence: Side-by-Side-Comparison Tables**

**Powered Muscle Stimulator**

| **Characteristics / Specifications** | **New Device**<br>**Stim2Go**<br>**K230701** | **Predicate Device**<br>**STIWELL med4**<br>**K080950** | **Comment** |
|---|---|---|---|
| **Basic Unit Characteristics** | | | |
| 510(k) Number | K230701 | K080950 | n.a. |
| Device Name, Model | Stim2Go | STIWELL med4 | n.a. |
| Manufacturer | Pajunk GmbH Medizintechnology | Otto Bock | n.a. |
| Power Source(s) | Battery Li-Ion 3.7 V (IEC 62133-2 certified) | Battery Pack Li-Ion 11 V | Substantially equivalent |
| - Method of Line Current Isolation | Medical class II Power adapter (5VDC - 10W, Globtek) | Medical class II Power adapter (12.6VDC - 15.1W, Mascot) | Substantially equivalent |
| Patient Leakage (Current Normal condition) | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| Patient Leakage Current (Single fault condition) | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| Number of Output Modes | 1 | 1 | Substantially equivalent |

| **Characteristics / Specifications** | **New Device**<br>**Stim2Go**<br>**K230701** | **Predicate Device**<br>**STIWELL med4**<br>**K080950** | **Comment** |
|---|---|---|---|
| Number of Output Channels | 5 | 4 | (PMS1) Substantially equivalent |
| - Synchronous or Alternating? | Alternating | Alternating | Substantially equivalent |
| - Method of Channel Isolation | Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state. | Transformer, Inductive couplers | (PMS2) Substantially equivalent |
| Regulated Current or Regulated Voltage? | Regulated current | Regulated current | Substantially equivalent |
| Software/Firmware/Microprocessor Control? | Yes | Yes | Substantially equivalent |
| Automatic Overload Trip? | Yes | Yes | Substantially equivalent |
| Automatic No-Load Trip? | Yes | Yes | Substantially equivalent |
| Automatic Shut Off? | Yes (15 min) | Yes (10 min) | Substantially equivalent |
| Patient Override Control? | Yes (STOP Button) | Yes (STOP Button) | Substantially equivalent |
| Indicator Display: | | | |

| **Characteristics / Specifications** | **New Device**<br>**Stim2Go**<br>**K230701** | **Predicate Device**<br>**STIWELL med4**<br>**K080950** | **Comment** |
|---|---|---|---|
| - On/Off Status? | Yes | Yes | Substantially equivalent |
| - Low Battery? | Yes | Yes | Substantially equivalent |
| - Voltage/Current Level? | Yes | Yes | Substantially equivalent |
| Timer Range (minutes) | 1-120 min | 2-120 min | Substantially equivalent |
| Compliance with Voluntary Standards? | IEC 60601, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304 | IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 | Substantially equivalent |
| Compliance with 21 CFR 898? | Yes | Yes | Substantially equivalent |
| Weight | 185 g | 440 g | Substantially equivalent |
| Dimensions (in.) [W x H x D] | 120 x 80 x 25 mm | 175 x 95 x 30 mm | Substantially equivalent |
| Housing Materials and Construction | Plastics | Plastics | Substantially equivalent |
| **Output Specifications** | | | |
| Waveform (e.g., pulsed monophasic, biphasic) | Biphasic symmetrical | Biphasic symmetrical | Substantially equivalent |

| **Characteristics / Specifications** | **New Device**<br>**Stim2Go**<br>**K230701** | **Predicate Device**<br>**STIWELL med4**<br>**K080950** | **Comment** |
|---|---|---|---|
| Shape (e.g., rectangular, spike, rectified sinusoidal) | Rectangular | Rectangular | Substantially equivalent |
| Maximum Output Voltage (500 Ω) | 50V @ 500 Ω | 50V @ 500 Ω | Substantially equivalent |
| Maximum Output Voltage (2 kΩ) | 115V @ 2 kΩ | 115V @ 2 kΩ | Substantially equivalent |
| Maximum Output Voltage (10 kΩ) | 115V @ 10 kΩ | 125V @ 10 kΩ (Measured) | (PMS3) Substantially equivalent |
| Maximum Output Current (500 Ω) | 100 mA @ 500 Ω | 100 mA @ 500 Ω | Substantially equivalent |
| Maximum Output Current (2 kΩ) | 50 mA @ 2 kΩ | 58 mA @ 2 kΩ | Substantially equivalent |
| Maximum Output Current (10 kΩ) | 11 mA @ 10 kΩ | 14 mA @ 10 kΩ (Measured) | (PMS3) Substantially equivalent |
| Pulse Width (specify units) | 30-400µs (default)<br>(30-750 µs in steps of 10 µs, adjustable only by therapists) | 50-400 µs | (PMS4) Substantially equivalent |
| Frequency (Hz) | 1,2,3,4,5,10,16,20,25,33, 50,100 Hz | 1 - 140 Hz | (PMS4) Substantially equivalent |
| For interferential modes only:<br>- Beat Frequency (Hz) | n/a | n/a | Substantially equivalent |

| **Characteristics / Specifications** | **New Device**<br>**Stim2Go**<br>**K230701** | **Predicate Device**<br>**STIWELL med4**<br>**K080950** | **Comment** |
|---|---|---|---|
| For multiphasic waveforms only:<br>- Symmetrical phases? | n/a | n/a | Substantially equivalent |
| For multiphasic waveforms only:<br>- Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical) | n/a | n/a | Substantially equivalent |
| Net Charge (m C per pulse): @500 Ω | 0 µC (Same positive and negative impulse) | 0 µC (Same positive and negative impulse) | Substantially equivalent |
| Maximum Phase Charge, (µC) @500 Ω | 75 µC (for 750 µs) | 40µC (for 400 µs) | (PMS5) Substantially equivalent |
| Maximum Current Density, (mA/cm²) @ 500 Ω | 12.5 mA / $cm^2$ | 12.5 mA / $cm^2$ | Substantially equivalent |
| Maximum Power Density, (W/cm²) @ 500 Ω (using smallest electrode conductive surface area) | 14.0 mW / $cm^2$ | 7.9 mW / $cm^2$ | Substantially equivalent |
| Burst Mode (i.e., pulse trains) a. Pulses per burst<br>b. Bursts per second<br>c. Burst duration (seconds)<br>d. Duty Cycle [Line (b) x Line (c)] | n/a n/a n/a n/a | n/a n/a n/a n/a | Substantially equivalent |
| ON Time (seconds) | 0.1 - 59 sec | 1 - 20 sec | Substantially equivalent |

| Characteristics / Specifications | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|
| OFF Time (seconds) | 0.1 - 59 sec | 1 - 50 sec | Substantially equivalent |
| Additional Features (if applicable) | n/a | n/a | Substantially equivalent |

**Discussion of Substantial Equivalence and Significant Differences**

(PMS1) Although the “Number of Output Channels” is different from the predicate device they both comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn’t impact essential performance, basic safety or substantial equivalence.

(PMS2) The channel isolation for both devices have been measured. Both measured isolation resistor values for the predicate and new device can only result in a maximum current from one channel to a different channel of 9 nA and 14 nA, respectively. In the standard IEC 60601-1 section 8.7.3 the allowable values of the touch current are 100 µA in normal condition is given. Hence, the touch current for both devices the new and the predicate device are factor 10000 lower than the maximum allowable value. Therefore, both tested devices comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn’t impact essential performance, basic safety, or substantial equivalence.

(PMS3) Both devices stop stimulating at low currents reporting an electrode error for a 10 kOhm load resistor. Therefore, the measured currents are very low.

(PMS4) The pulse width and frequency used in the standard powered muscle stimulation programs are substantially equivalent to the corresponding programs and default settings of the predicate device. The new device has a lower maximum frequency (100 Hz) and a higher maximum pulse width (750µs) compared to the predicate device. Both parameters can only be adjusted by therapists (e.g., for patients with high BMI). Both tested devices comply with the requirements of IEC 60601-1 and IEC 60601-2-10. The differences in pulse width and frequency do not impact essential performance, effectiveness, safety, or substantial equivalence.

(PMS5) A maximum pulse width of 750µs and a maximum current amplitude of 100 mA results in a maximum phase charge of 75µC, which is considered safe (classification 21CFR890.5850). In addition, both tested devices comply with the requirements of IEC 60601-1 and IEC 60601-2-10. The difference in maximum phase charge doesn’t impact essential performance, effectiveness, safety, or substantial equivalence.

None of these differences, raise any new issues of safety or effectiveness of the new device compared to the predicate device. All respective standards have been applied during compliance testing.

**Functional Electrical Stimulation Programs (non-triggered):**

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| ***Basis Units Characteristics*** | | | | | |
| **Program** | Grasp and Release | FES 1 Grasp/Release | Open and Close | FES 3 Open / Close | n/a |
| **510(k) Numbers** | K230701 | K080950 | K230701 | K080950 | n/a |
| **Manufacturer** | Pajunk GmbH Medizintechnology | Otto Bock | Pajunk GmbH Medizintechnology | Otto Bock | n/a |
| **Device Name, Model** | Stim2Go | STIWELL med4 | Stim2Go | STIWELL med4 | n/a |
| **Power Source(s)** | Battery Li-Ion 3.7 V (IEC 62133-2 certified) | Battery Pack Li-Ion 11 V | Battery Li-Ion 3.7 V (IEC 62133-2 certified) | Battery Pack Li-Ion 11 V | Substantially equivalent |
| **Method of Line Current Isolation** | Medical class II Power adapter (5VDC - 10W, Globtek) | Medical class II Power adapter (12.6VDC - 15.1W, Mascot) | Medical class II Power adapter (5VDC - 10W, Globtek) | Medical class II Power adapter (12.6VDC - 15.1W, Mascot) | Substantially equivalent |
| **Leakage Current (normal condition)** | n/a (Battery) | n/a (Battery) | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| **Leakage Current (single fault condition)** | n/a (Battery) | n/a (Battery) | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| **No. Output Mod.** | 1 | 1 | 1 | 1 | Substantially equivalent |
| **No. Output Chan.** | 3 | 3 | 3 | 3 | Substantially equivalent |
| **Stimulated Muscle(s)** | Wrist extensors<br>Finger flexors<br>Thumb flexor | Wrist extensors<br>Finger flexors<br>Thumb flexor | Finger/thumb extensors<br>Finger flexors<br>Thumb flexor | Finger/thumb extensors<br>Finger flexors<br>Thumb flexor | Substantially equivalent |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| **No. of Sensor Channels** | 0 | 0 | 0 | 0 | Substantially equivalent |
| **Sensor Sensitivity** | n/a | n/a | n/a | n/a | Substantially equivalent |
| **Sensor Sample Rate** | n/a | n/a | n/a | n/a | Substantially equivalent |
| **Sensor Detection** | n/a | n/a | n/a | n/a | Substantially equivalent |
| **Sensor Range** | n/a | n/a | n/a | n/a | Substantially equivalent |
| **Sensor Bandwidth** | n/a | n/a | n/a | n/a | Substantially equivalent |
| **Sensor Signal Proc.** | n/a | n/a | n/a | n/a | |
| **Synchr. Or Altern.?** | Alternating | Alternating | Alternating | Alternating | Substantially equivalent |
| **Meth. Chan. Isol.** | Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state. | Transformer, Inductive couplers | Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state. | Transformer, Inductive couplers | (FES1) Substantially equivalent |
| **Regulated Current or Regulated Voltage?** | Regulated current | Regulated current | Regulated current | Regulated current | Substantially equivalent |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| **Software /Firmware/ Microprocessor Control?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **Automatic Overload Trip?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **Automatic No-Load Trip?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **Automatic Shut Off?** | Yes (15 min) | Yes (10 min) | Yes (15 min) | Yes (10 min) | Substantially equivalent |
| **Patient Override Control?** | Yes (STOP Button) | Yes (STOP Button) | Yes (STOP Button) | Yes (STOP Button) | Substantially equivalent |
| **Indicator Display:** | | | | | |
| **- On/Off Status?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **- Low Battery?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **- Voltage/Current Level?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **Timer Range (minutes)** | 1-60; default 30 min | 15-60 | 1-60; default 30 min | 15-60 | Substantially equivalent |
| **Compliance with Voluntary Standards?** | IEC 60601, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304 | IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 | IEC 60601, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304 | IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 | Substantially equivalent |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| **Compliance with 21 CFR 898?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **Weight** | 185 g | 440 g | 185 g | 440 g | Substantially equivalent |
| **Dimensions (in.) [W x H x D]** | 120 x 80 x 25 mm | 175 x 95 x 30 mm | 120 x 80 x 25 mm | 175 x 95 x 30 mm | Substantially equivalent |
| **Housing Materials and Construction** | Plastics | Plastics | Plastics | Plastics | Substantially equivalent |
| **Output Specification** | | | | | |
| **Waveform** | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical | Substantially equivalent |
| Rectangular | Rectangular | Rectangular | Rectangular | Rectangular | Substantially equivalent |
| **Maximum Output Voltage (500 Ω)** | 50V @ 500 Ω | 50V @ 500 Ω | 50V @ 500 Ω | 50V @ 500 Ω | Substantially equivalent |
| **Maximum Output Voltage (2 kΩ)** | 115V @ 2 kΩ | 115V @ 2 kΩ | 115V @ 2 kΩ | 115V @ 2 kΩ | Substantially equivalent |
| **Maximum Output Voltage (10 kΩ)** | 115V @ 10 kΩ | 125V @ 10 kΩ (Measured) | 115V @ 10 kΩ | 125V @ 10 kΩ (Measured) | (FES2) Substantially equivalent |
| **Maximum Output Current (500 Ω)** | 100 mA @ 500 Ω | 100 mA @ 500 Ω | 100 mA @ 500 Ω | 100 mA @ 500 Ω | Substantially equivalent |
| **Maximum Output Current (2 kΩ)** | 50 mA @ 2 kΩ | 58 mA @ 2 kΩ | 50 mA @ 2 kΩ | 58 mA @ 2 kΩ | Substantially equivalent |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| **Maximum Output Current (10 kΩ)** | 11 mA @ 10 kΩ | 14 mA @ 10 kΩ (Measured) | 11 mA @ 10 kΩ | 14 mA @ 10 kΩ (Measured) | (FES2) Substantially equivalent |
| **Pulse Width (specify units)** | 30-400µs (default)<br>(30-750 µs in steps of 10 µs, adjustable only by therapists) | 50-400µs | 30-400µs (default)<br>(30-750 µs in steps of 10 µs, adjustable only by therapists) | 50-400µs | (FES3) Substantially equivalent |
| **Frequency (Hz)** | 1-100Hz (default 33 Hz) | 1-140 Hz; default 35 Hz | 1-100Hz (default 33 Hz) | 1-140 Hz; default 35 Hz | (FES3) Substantially equivalent |
| **Net Charge [µC] (500 Ω)** | 0 µC (Same positive and negative impulse) | 0 µC (Same positive and negative impulse) | 0 µC (Same positive and negative impulse) | 0 µC (Same positive and negative impulse) | Substantially equivalent |
| **Maximum Phase Charge [µC] (500 Ω)** | 75 µC (for 750 µs) | 40 µC (for 400 µs) | 75 µC (for 750 µs) | 40 µC (for 400 µs) | (FES4) Substantially equivalent |
| **Maximum Current Density [mA/cm$^2$] (500 Ω)** | 12.5 mA/cm$^2$ | 12.5 mA/cm$^2$ | 12.5 mA/cm$^2$ | 12.5 mA/cm$^2$ | Substantially equivalent |
| **Maximum Power Density [W/cm$^2$] (500 Ω)** | 14 mW / cm^2 | 7.9 mW/cm$^2$ | 14 mW / cm^2 | 7.9 mW/cm$^2$ | Substantially equivalent |
| **Burst Mode (i.e., pulse trains): Pulses per burst** | n/a | n/a | n/a | n/a | n/a |
| **Burst Mode (i.e., pulse trains): Bursts per second** | n/a | n/a | n/a | n/a | n/a |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| **Burst Mode (i.e., pulse trains): Burst duration (seconds)** | n/a | n/a | n/a | n/a | n/a |
| **Duty Cycle [Line (b) x Line (c)]** | n/a | n/a | n/a | n/a | n/a |
| **ON Time [seconds]** | 1-60 s; default 20 | 1-20 s | 1-60 s; default 20 | 1 – 20 s | Substantially equivalent |
| **OFF Time [seconds]** | 1-60 s; default 30 | 1-30 s | 1-60 s; default 20 | 1 – 30 s | Substantially equivalent |
| **Additional features** | n/a | n/a | n/a | n/a | n/a |

**Functional Electrical Stimulation Programs (triggered):**

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| ***Basis Units Characteristics*** | | | | | |
| **Program** | Triggered Grasp and Release | FES 2 Grasp/Release | Triggered Open and Close | FES 4 Open / Close | n/a |
| **510(k) Numbers** | K230701 | K080950 | K230701 | K080950 | n/a |
| **Manufacturer** | Pajunk GmbH Medizintechnology | Otto Bock | Pajunk GmbH Medizintechnology | Otto Bock | n/a |
| **Device Name, Model** | Stim2Go | STIWELL med4 | Stim2Go | STIWELL med4 | n/a |
| **Power Source(s)** | Battery Li-Ion 3.7 V (IEC 62133-2 certified) | Battery Pack Li-Ion 11 V | Battery Li-Ion 3.7 V (IEC 62133-2 certified) | Battery Pack Li-Ion 11 V | Substantially equivalent |
| **Method of Line Current Isolation** | Medical class II Power adapter (5VDC - 10W, Globtek) | Medical class II Power adapter (12.6VDC - 15.1W, Mascot) | Medical class II Power adapter (5VDC - 10W, Globtek) | Medical class II Power adapter (12.6VDC - 15.1W, Mascot) | Substantially equivalent |
| **Leakage Current (normal condition)** | n/a (Battery) | n/a (Battery) | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| **Leakage Current (single fault condition)** | n/a (Battery) | n/a (Battery) | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| **No. Output Mod.** | 1 | 1 | 1 | 1 | Substantially equivalent |
| **No. Output Chan.** | 3 | 3 | 3 | 3 | Substantially equivalent |
| **Stimulated Muscle(s)** | Wrist extensors<br>Finger flexors<br>Thumb flexor | Wrist extensors<br>Finger flexors<br>Thumb flexor | Finger/thumb extensors<br>Finger flexors<br>Thumb flexor | Finger/thumb extensors<br>Finger flexors<br>Thumb flexor | Substantially equivalent |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| **No. of Sensor Channels** | 1 | 1 | 1 | 1 | (FES5) Substantially equivalent |
| **Sensor Sensitivity** | 1 degree (inclination angle) | 1 uV (EMG) | 1 degree (inclination angle) | 1 uV (EMG) | (FES5) Substantially equivalent |
| **Sensor Sample Rate** | 200 Hz (inclination angle) | 3 kHz (EMG) | 200 Hz (inclination angle) | 3 kHz (EMG) | (FES5) Substantially equivalent |
| **Sensor Detection** | n/a | Bipolar (EMG) | n/a | Bipolar (EMG) | (FES5) Substantially equivalent |
| **Sensor Range** | -80° to +80° (inclination angle) | 1-2000 µV (EMG) | -80° to +80° (inclination angle) | 1-2000 µV (EMG) | (FES5) Substantially equivalent |
| **Sensor Bandwidth** | 0 – 50 Hz (inclination angle) | 70 – 480 Hz (EMG) | 0 – 50 Hz (inclination angle) | 70 – 480 Hz (EMG) | (FES5) Substantially equivalent |
| **Sensor Signal Proc.** | Inclination calculation via complementary filter | AVR (Averaged Rectified value) | Inclination calculation via complementary filter | AVR (Averaged Rectified value) | (FES5) Substantially equivalent |
| **Synchr. Or Altern.?** | Alternating | Alternating | Alternating | Alternating | Substantially equivalent |
| **Meth. Chan. Isol.** | Each channel is the middle of a H-bridge. Except when it is activated, each channel | Transformer, Inductive couplers | Each channel is the middle of a H-bridge. Except when it is | Transformer, Inductive couplers | (FES1) Substantially equivalent |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| | is always in high impedance state. | | activated, each channel is always in high impedance state. | | |
| **Regulated Current or Regulated Voltage?** | Regulated current | Regulated current | Regulated current | Regulated current | Substantially equivalent |
| **Software /Firmware/ Microprocessor Control?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **Automatic Overload Trip?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **Automatic No-Load Trip?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **Automatic Shut Off?** | Yes (15 min) | Yes (10 min) | Yes (15 min) | Yes (10 min) | Substantially equivalent |
| **Patient Override Control?** | Yes (STOP Button) | Yes (STOP Button) | Yes (STOP Button) | Yes (STOP Button) | Substantially equivalent |
| **Indicator Display:** | | | | | |
| **- On/Off Status?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **- Low Battery?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **- Voltage/Current Level?** | Yes | Yes | Yes | Yes | Substantially equivalent |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| **Timer Range (minutes)** | 1-60 min; default 30 min | 15-60 min | 1-60 min; default 30 min | 15-60 min | Substantially equivalent |
| **Compliance with Voluntary Standards?** | IEC 60601, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304 | IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 | IEC 60601, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304 | IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 | Substantially equivalent |
| **Compliance with 21 CFR 898?** | Yes | Yes | Yes | Yes | Substantially equivalent |
| **Weight** | 185 g | 440 g | 185 g | 440 g | Substantially equivalent |
| **Dimensions (in.) [W x H x D]** | 120 x 80 x 25 mm | 175 x 95 x 30 mm | 120 x 80 x 25 mm | 175 x 95 x 30 mm | Substantially equivalent |
| **Housing Materials and Construction** | Plastics | Plastics | Plastics | Plastics | Substantially equivalent |
| **Output Specification** | | | | | |
| **Waveform** | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical | Substantially equivalent |
| Rectangular | Rectangular | Rectangular | Rectangular | Rectangular | Substantially equivalent |
| **Maximum Output Voltage (500 Ω)** | 50V @ 500 Ω | 50V @ 500 Ω | 50V @ 500 Ω | 50V @ 500 Ω | Substantially equivalent |
| **Maximum Output Voltage (2 kΩ)** | 115V @ 2 kΩ | 115V @ 2 kΩ | 115V @ 2 kΩ | 115V @ 2 kΩ | Substantially equivalent |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| **Maximum Output Voltage (10 kΩ)** | 115V @ 10 kΩ | 125V @ 10 kΩ (Measured) | 115V @ 10 kΩ | 125V @ 10 kΩ (Measured) | (FES2) Substantially equivalent |
| **Maximum Output Current (500 Ω)** | 100 mA @ 500 Ω | 100 mA @ 500 Ω | 100 mA @ 500 Ω | 100 mA @ 500 Ω | Substantially equivalent |
| **Maximum Output Current (2 kΩ)** | 50 mA @ 2 kΩ | 58 mA @ 2 kΩ | 50 mA @ 2 kΩ | 58 mA @ 2 kΩ | Substantially equivalent |
| **Maximum Output Current (10 kΩ)** | 11 mA @ 10 kΩ | 14 mA @ 10 kΩ (Measured) | 11 mA @ 10 kΩ | 14 mA @ 10 kΩ (Measured) | (FES2) Substantially equivalent |
| **Pulse Width (specify units)** | 30-400µs (default)<br>(30-750 µs in steps of 10 µs, adjustable only by therapists)) | 50-400µs | 30-400µs (default)<br>(30-750 µs in steps of 10 µs, adjustable only by therapists) | 50-400µs | (FES3) Substantially equivalent |
| **Frequency (Hz)** | 1-100Hz (default 33 Hz) | 1-140 Hz; default 35 Hz | 1-100Hz (default 33 Hz) | 1-140 Hz; default 35 Hz | (FES3) Substantially equivalent |
| **Net Charge [µC] (500 Ω)** | 0 µC (Same positive and negative impulse) | 0 µC (Same positive and negative impulse) | 0 µC (Same positive and negative impulse) | 0 µC (Same positive and negative impulse) | Substantially equivalent |
| **Maximum Phase Charge [µC] (500 Ω)** | 75 µC | 40 µC | 75 µC | 40 µC | (FES4) Substantially equivalent |
| **Maximum Current Density [mA/cm$^2$] (500 Ω)** | 12.5 mA/cm$^2$ | 12.5 mA/cm$^2$ | 12.5 mA/cm$^2$ | 12.5 mA/cm$^2$ | Substantially equivalent |

| Characteristics / Specifications | New Device | Predicate Device | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|---|---|
| **Maximum Power Density [W/cm$^2$] (500 Ω)** | 14 mW / cm^2 | 7.9 mW/cm$^2$ | 14 mW / cm^2 | 7.9 mW/cm$^2$ | Substantially equivalent |
| **Burst Mode (i.e., pulse trains): Pulses per burst** | n/a | n/a | n/a | n/a | n/a |
| **Burst Mode (i.e., pulse trains): Bursts per second** | n/a | n/a | n/a | n/a | n/a |
| **Burst Mode (i.e., pulse trains): Burst duration (seconds)** | n/a | n/a | n/a | n/a | n/a |
| **Duty Cycle [Line (b) x Line (c)]** | n/a | n/a | n/a | n/a | n/a |
| **ON Time [seconds]** | 1-60 s; default 20 | 1-20 s | 1-60 s; default 20 | 1 – 20 s | Substantially equivalent |
| **OFF Time [seconds]** | Trigger controlled (min. 1 - 60s) | Trigger controlled (min. 1 - 30s) | Trigger controlled (min. 1 - 60s) | Trigger controlled (min. 1 - 30s) | Substantially equivalent |
| **Additional features** | n/a | n/a | n/a | n/a | n/a |

**Discussion of Substantial Equivalence and Significant Differences**

(FES1) The channel isolation for both devices have been measured. Both measured isolation resistor values for the predicate and new device can only result in a maximum current from one channel to a different channel of 9 nA and 14 nA, respectively. In the standard IEC 60601-1 section 8.7.3 the allowable values of the touch current are 100 µA in normal condition is given. Hence, the touch current for both devices the new and the predicate device are factor 10000 lower than the maximum allowable value. Therefore, both tested devices comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn't impact essential performance, basic safety, or substantial equivalence.

(FES2) Both devices stop stimulating at low currents reporting an electrode error for a 10 kOhm load resistor. Therefore, the measured currents are very low.

(FES3) The pulse width and frequency used in the standard FES programs are substantially equivalent to the corresponding programs and default settings of the predicate device. The new device has a lower maximum frequency (100 Hz) and a higher maximum pulse width (750µs) compared to the predicate device. Both parameters can only be adjusted by therapists (e.g., for patients with high BMI). Both tested devices comply with the requirements of IEC 60601-1 and IEC 60601-2-10. The differences in pulse width and frequency do not impact essential performance, effectiveness, safety, or substantial equivalence.

(FES4) A maximum pulse width of 750µs and a maximum current amplitude of 100 mA results in a maximum phase charge of 75µC, which is considered safe (classification 21CFR882.5810). In addition, both tested devices comply with the requirements of IEC 60601-1 and IEC 60601-2-10. The difference in maximum phase charge doesn't impact essential performance, effectiveness, safety, or substantial equivalence.

(FES5) The stimulator has a built-in inertial sensor consisting of a 3D accelerometer and a 3D gyroscope. Using the raw data, a complementary filter running at 200 Hz calculates the inclination angle of the stimulator. When the stimulator is placed at specific positions on the upper or lower limbs by means of a strap, the patient's weak movements, i.e., changes in the limb inclination, can be captured and used to trigger specific functional electrical stimulation patterns. EMG activity (used in the predicate device) and changes in limb inclination (used in the new device) are physiologically linked and occur almost simultaneously. Therefore, the subject device and predicate device both use sensor technologies that capture the residual motor function of the patient to trigger a stimulation sequence for movement support and completion.

However, some active Range of Motion (ROM) is needed for the subject device with movement-based trigger. In contrast, in the case of EMG-based biofeedback, a patient could have muscle twitching without active ROM and this would allow the EMG based biofeedback to trigger the stimulation parameter even without active ROM. Therefore, the subject device is only effective for patients with active ROM. This limitation is prominently displayed in the indications of use.

After triggering, the applied electrical stimulation is equivalent in both devices. Safety and effectiveness of the intervention (electrical stimulation) are not affected by the different sensor technologies used in the subject and predicate device.

We conclude that the inclination-triggered FES programs of the subject device are substantially equivalent to the EMG-triggered FES programs of the predicate device in effectiveness and safety for patients with an active range of motion (ROM) which is defined as the ability of volitional movement resulting in a change of the concerned limb inclination angle of at least 10 degrees (derived from the sensor range).

**Biofeedback:**

| Characteristics / Specifications | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|
| ***Basis Units Characteristics*** | | | |
| **510(k) Numbers** | K230701 | K080950 | n/a |
| **Manufacturer** | Pajunk GmbH Medizintechnology | Otto Bock | n/a |
| **Device Name, Model** | Stim2Go | STIWELL med4 | n/a |
| **Power Source(s)** | Battery Li-Ion 3.7 V (IEC 62133-2 certified) | Battery Pack Li-Ion 11 V | Substantially equivalent |
| **Method of Line Current Isolation** | Medical class II Power adapter (5VDC - 10W, Globtek) | Medical class II Power adapter (12.6VDC - 15.1W, Mascot) | Substantially equivalent |
| **Leakage Current (normal condition)** | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| **Leakage Current (single fault condition)** | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| **No. Output Mod.** | 1 | 1 | Substantially equivalent |
| **No. Output Chan.** | 1 | 1 | Substantially equivalent |
| **No. of Sensor Channels** | 1 | 2 | (BF1) Substantially equivalent |
| **Sensor Sensitivity** | 1 degree (inclination angle) | 1 uV (EMG) | (BF1) Substantially equivalent |
| **Sensor Sample Rate** | 200 Hz (inclination angle) | 3 kHz (EMG) | (BF1) Substantially equivalent |
| **Sensor Detection** | n/a | Bipolar (EMG) | (BF1) Substantially equivalent |
| **Sensor Range** | -80° to +80° (inclination angle) | 1-2000 µV (EMG) | (BF1) Substantially equivalent |
| **Sensor Bandwidth** | 0 – 50 Hz (inclination angle) | 70 – 480 Hz (EMG) | (BF1) Substantially equivalent |
| **Sensor Signal Proc.** | Inclination calculation via complementary filter | AVR (Averaged Rectified value) | (BF1) Substantially equivalent |

| Characteristics / Specifications | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|
| **Synchr. or Altern.?** | n/a | n/a | n/a |
| **Method of Channel Isolation** | n/a | n/a | n/a |
| **Regulated Current or Regulated Voltage?** | n/a | n/a | n/a |
| **Software /Firmware/ Microprocessor Control?** | n/a | n/a | n/a |
| **Automatic Overload Trip?** | n/a | n/a | n/a |
| **Automatic No-Load Trip?** | n/a | n/a | n/a |
| **Automatic Shut Off?** | Yes (15 min) | Yes (10 min) | Substantially equivalent |
| **Patient Override Control?** | Yes (STOP Button) | Yes (STOP Button) | Substantially equivalent |
| **Indicator Display:** | | | |
| **- On/Off Status?** | Yes | Yes | Substantially equivalent |
| **- Low Battery?** | Yes | Yes | Substantially equivalent |
| **- Voltage/Current Level?** | n/a | n/a | n/a |
| **Timer Range (minutes)** | 1-60 min; default 30 min | 15-30 min | Substantially equivalent |
| **Compliance with Voluntary Standards?** | IEC 60601, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304 | IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 | Substantially equivalent |
| **Compliance with 21 CFR 898?** | Yes | Yes | Substantially equivalent |
| **Weight** | 185 g | 440 g | Substantially equivalent |
| **Dimensions [W x H x D] in [mm]** | 120 x 80 x 25 mm | 175 x 95 x 30 mm | Substantially equivalent |
| **Housing Materials and Construction** | Plastics | Plastics | Substantially equivalent |

| **Characteristics / Specifications** | **New Device**<br>Stim2Go<br>K230701 | **Predicate Device**<br>STIWELL med4<br>K080950 | **Comment** |
|---|---|---|---|
| **Output Specification** | | | |
| **Waveform** | n/a | n/a | n/a |
| Rectangular | n/a | n/a | n/a |
| **Maximum Output Voltage (500 Ω)** | n/a | n/a | n/a |
| **Maximum Output Voltage (2 kΩ)** | n/a | n/a | n/a |
| **Maximum Output Voltage (10 kΩ)** | n/a | n/a | n/a |
| **Maximum Output Current (500 Ω)** | n/a | n/a | n/a |
| **Maximum Output Current (2 kΩ)** | n/a | n/a | n/a |
| **Maximum Output Current (10 kΩ)** | n/a | n/a | n/a |
| **Pulse Width (specify units)** | n/a | n/a | n/a |
| **Frequency (Hz)** | n/a | n/a | n/a |
| **For interferential modes only: Beat Frequency [Hz]** | n/a | n/a | n/a |
| **For multiphasic wave forms only: Symmetricl Phases?** | n/a | n/a | n/a |
| **For multiphasic wave forms only: Phase duration (incl. units);** | n/a | n/a | n/a |
| **Net Charge [µC] (500 Ω)** | n/a | n/a | n/a |
| **Maximum Phase Charge [µC] (500 Ω)** | n/a | n/a | n/a |

| Characteristics / Specifications | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|
| **Maximum Current Density [mA/cm$^2$] (500 Ω)** | n/a | n/a | n/a |
| **Maximum Power Density [W/cm$^2$] (500 Ω)** | n/a | n/a | n/a |
| **Burst Mode (i.e., pulse trains): Pulses per burst** | n/a | n/a | n/a |
| **Burst Mode (i.e., pulse trains): Bursts per second** | n/a | n/a | n/a |
| **Burst Mode (i.e., pulse trains): Burst duration (seconds)** | n/a | n/a | n/a |
| **Burst Mode (i.e., pulse trains): Duty Cycle [Line (b) x Line (c)]** | n/a | n/a | n/a |
| **ON Time [seconds]** | n/a | n/a | n/a |
| **OFF Time [seconds]** | n/a | n/a | n/a |
| **Additional features** | n/a | n/a | n/a |

**Discussion of Substantial Equivalence and Significant Differences**

(BF1) The stimulator has a built-in inertial sensor consisting of a 3D accelerometer and a 3D gyroscope. Using the raw data, a complementary filter running at 200 Hz calculates the inclination angle of the stimulator. When the stimulator is placed at specific positions on the upper or lower limbs by means of a strap, the patient's weak movements, i.e., changes in the limb inclination, can be captured and used to trigger specific functional electrical stimulation patterns. EMG activity (used in the predicate device) and changes in limb inclination (used in the new device) are physiologically linked and occur almost simultaneously. Therefore, the subject device and predicate device both use sensor technologies that capture the residual motor function of the patient for biofeedback.

However, some active Range of Motion (ROM) is needed for the subject device to detect residual motion. In contrast, in the case of EMG-based biofeedback, a patient could have muscle twitching without active ROM and this would allow the EMG based biofeedback even without active ROM. Therefore, the subject device is only effective for the patients with active ROM.

We conclude that the biofeedback in effectiveness and safety for patients with an active range of motion (ROM) which is defined as the ability of volitional movement resulting in a change of the concerned limb inclination angle of at least 10 degrees (derived from the sensor range).

**TENS:**

| Characteristics / Specifications | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|
| ***Basis Units Characteristics*** | | | |
| **510(k) Numbers** | K230701 | K080950 | n/a |
| **Manufacturer** | Pajunk GmbH Medizintechnology | Otto Bock | n/a |
| **Device Name, Model** | Stim2Go | STIWELL med4 | n/a |
| **Power Source(s)** | Battery Li-Ion 3.7 V (IEC 62133-2 certified) | Battery Pack Li-Ion 11 V | Substantially equivalent |
| **Method of Line Current Isolation** | Medical class II Power adapter (5VDC - 10W, Globtek) | Medical class II Power adapter (12.6VDC - 15.1W, Mascot) | Substantially equivalent |
| **Leakage Current (normal condition)** | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| **Leakage Current (single fault condition)** | n/a (Battery) | n/a (Battery) | Substantially equivalent |
| **No. Output Mod.** | 1 | 1 | Substantially equivalent |
| **No. Output Chan.** | 4 | 4 | Substantially equivalent |
| **No. of Sensor Channels** | n/a | n/a | n/a |
| **Sensor Sensitivity** | n/a | n/a | n/a |
| **Sensor Sample Rate** | n/a | n/a | n/a |
| **Sensor Detection** | n/a | n/a | n/a |
| **Sensor Range** | n/a | n/a | n/a |
| **Sensor Bandwidth** | n/a | n/a | n/a |
| **Sensor Signal Proc.** | n/a | n/a | n/a |
| **Synchr. or Altern.?** | Alternating | Alternating | Substantially equivalent |

| Characteristics / Specifications | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|
| **Method of Channel Isolation** | Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state. | Transformer, Inductive couplers | (TENS1) Substantially equivalent |
| **Regulated Current or Regulated Voltage?** | Regulated current | Regulated current | Substantially equivalent |
| **Software /Firmware/ Microprocessor Control?** | Yes | Yes | Substantially equivalent |
| **Automatic Overload Trip?** | Yes | Yes | Substantially equivalent |
| **Automatic No-Load Trip?** | Yes | Yes | Substantially equivalent |
| **Automatic Shut Off?** | Yes (15 min) | Yes (10 min) | Substantially equivalent |
| **Patient Override Control?** | Yes (STOP Button) | Yes (STOP Button) | Substantially equivalent |
| **Indicator Display:** | | | |
| **- On/Off Status?** | Yes | Yes | Substantially equivalent |
| **- Low Battery?** | Yes | Yes | Substantially equivalent |
| **- Voltage/Current Level?** | Yes | Yes | Substantially equivalent |
| **Timer Range (minutes)** | 1-60; default 30 min | 10-120 min | Substantially equivalent |
| **Compliance with Voluntary Standards?** | IEC 60601, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304 | IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 | Substantially equivalent |
| **Compliance with 21 CFR 898?** | Yes | Yes | Substantially equivalent |
| **Weight** | 185 g | 440 g | Substantially equivalent |
| **Dimensions (in.) [W x H x D]** | 120 x 80 x 25 mm | 175 x 95 x 30 mm | Substantially equivalent |
| **Housing Materials and Construction** | Plastics | Plastics | Substantially equivalent |

| **Characteristics / Specifications** | **New Device**<br>Stim2Go<br>K230701 | **Predicate Device**<br>STIWELL med4<br>K080950 | **Comment** |
|---|---|---|---|
| **Output Specification** | | | |
| **Waveform** | Biphasic symmetrical | Biphasic symmetrical | Substantially equivalent |
| Rectangular | Rectangular | Rectangular | Substantially equivalent |
| **Maximum Output Voltage (500 Ω)** | 50V @ 500 Ω | 50V @ 500 Ω | Substantially equivalent |
| **Maximum Output Voltage (2 kΩ)** | 115V @ 2 kΩ | 115V @ 2 kΩ | Substantially equivalent |
| **Maximum Output Voltage (10 kΩ)** | 115V @ 10 kΩ | 125V @ 10 kΩ (Measured) | (TENS2) Substantially equivalent |
| **Maximum Output Current (500 Ω)** | 100 mA @ 500 Ω | 100 mA @ 500 Ω | Substantially equivalent |
| **Maximum Output Current (2 kΩ)** | 50 mA @ 2 kΩ | 58 mA @ 2 kΩ | Substantially equivalent |
| **Maximum Output Current (10 kΩ)** | 11 mA @ 10 kΩ | 14 mA @ 10 kΩ (Measured) | (TENS2) Substantially equivalent |
| **Pulse Width (specify units)** | 150-200 µs | 150-200 µs | Substantially equivalent |
| **Frequency (Hz)** | 2-100 Hz | 2-100 Hz | Substantially equivalent |
| **Net Charge [µC] (500 Ω)** | 0 µC (Same positive and negative impulse) | 0 µC (Same positive and negative impulse) | Substantially equivalent |
| **Maximum Phase Charge [µC] (500 Ω)** | 20 µC | 20 µC | Substantially equivalent |
| **Maximum Current Density [mA/cm$^2$] (500 Ω)** | 12.5 mA/cm$^2$ | 12.5 mA/cm$^2$ | Substantially equivalent |
| **Maximum Power Density [W/cm$^2$] (500 Ω)** | 1 mW/cm$^2$ | 1 mW/cm$^2$ | Substantially equivalent |
| **Burst Mode (i.e., pulse trains): Pulses per burst** | 8 | 8 | Substantially equivalent |
| **Burst Mode (i.e., pulse trains): Bursts per second** | 2 | 2 | Substantially equivalent |

| Characteristics / Specifications | New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | Comment |
|---|---|---|---|
| **Burst Mode (i.e., pulse trains): Burst duration (seconds)** | 100ms | 100ms | Substantially equivalent |
| **Burst Mode (i.e. pilse trains): Duty Cycle [Line (b) x Line (c)]** | 20% | 20% | Substantially equivalent |
| **ON Time [seconds]** | Continuous or Burst | Continuous or Burst | Substantially equivalent |
| **OFF Time [seconds]** | n/a | n/a | n/a |
| **Additional features** | n/a | n/a | n/a |

**Discussion of Substantial Equivalence and Significant Differences**

(TENS1) The channel isolation for both devices have been measured. Both measured isolation resistor values for the predicate and new device can only result in a maximum current from one channel to a different channel of 9 nA and 14 nA, respectively. In the standard IEC 60601-1 section 8.7.3 the allowable values of the touch current are 100 µA in normal condition is given. Hence, the touch current for both devices the new and the predicate device are factor 10000 lower than the maximum allowable value. Therefore, both tested devices comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn't impact essential performance, basic safety, or substantial equivalence.

(TENS2) Both devices stop stimulating at low currents reporting an electrode error for a 10 kOhm load resistor. Therefore, the measured currents are very low.

**Discussion:**

None of these differences, raise any new issues of safety or effectiveness of the new device compared to the predicate device. All respective standards have been applied during compliance testing.

**Indications for use**

| **New Device**<br>**Stim2Go**<br>**K230701** | **Predicate Device**<br>**STIWELL med4**<br>**K080950** | |
|---|---|---|
| **IFU Stim2Go** | **IFU Stiwell Med 4** | **Discussion/ Comment** |
| As a powered muscle stimulator (NMES) the Stim2Go is indicated for the following conditions:<br><br>* Relaxation of muscle spasm<br><br>* Prevention or retardation of disuse atrophy<br><br>* Increasing local blood circulation<br><br>* Muscle re-education<br><br>* Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis<br><br>* Maintaining or increasing range of motion | The STIWELL med4 is a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.<br><br>As a powered muscle stimulator the STIWELL med4 is indicated for the following conditions:<br><br>* Relaxation of muscle spasm<br><br>* Prevention or retardation of disuse atrophy<br><br>* Increasing local blood circulation<br><br>* Muscle re-education<br><br>* Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis<br><br>* Maintaining or increasing range of motion | Substantially Equivalent |
| As a transcutaneous electrical nerve stimulator (TENS) for pain the Stim2Go is indicated for the following conditions: | As a transcutaneous electrical nerve stimulator for pain relief the STIWELL med4 is indicated for the following conditions: | Substantially Equivalent |

| **New Device**<br>**Stim2Go**<br>**K230701** | **Predicate Device**<br>**STIWELL med4**<br>**K080950** | |
|---|---|---|
| * Symptomatic relief and management of chronic (long-term), intractable pain<br>* Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain | * Symptomatic relief and management of chronic (long-term), intractable pain<br>* Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain | |
| As a biofeedback device the Stim2Go is indicated for the following condition:<br>* Muscle re-education purposes<br>The movement-based biofeedback can only be used for patients with an active range of motion (ROM) which is defined as the ability of volitional movement resulting in a change of the concerned limb inclination angle of at least 10 degrees. | As a biofeedback device the STIWELL med4 is indicated for the following conditions:<br>* Biofeedback, relaxation and muscle re-education purposes | Substantially Equivalent (1) |
| As a functional neuromuscular stimulator the Stim2Go is indicated for the following conditions:<br>* Helps to relearn voluntary motor functions of the extremities | As an external functional neuromuscular stimulator the STIWELL med4 is indicated for the following conditions:<br>* Helps to relearn voluntary motor functions of the extremities | Substantially Equivalent (1) |
| n/a | As a nonimplanted electrical continence device the STIWELL mad4 is indicated for the following conditions:<br>* Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through | n/a (2) |

| New Device<br>Stim2Go<br>K230701 | Predicate Device<br>STIWELL med4<br>K080950 | |
|---|---|---|
| | reflexive mechanisms and strengthening of pelvic floor muscles<br><br>* Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles | |

**Discussion of Substantial Equivalence and Significant Differences**

(1) Compared to the predicate device, Stim2Go offers biofeedback based on the built-in inertial sensor by assessing changes in a limb's inclination angle. This yields substantial equivalence compared to the EMG-biofeedback technology of the predicate device for patients with an active Range of Motion (ROM) which is defined as the ability of volitional movement resulting in a change of the concerned limb inclination angle of at least 10 degrees. This limitation is prominently displayed in the indications of use.

(2) Compared to the predicate device the Stim2Go is **not** indicated nonimplanted electrical continence device.

Further indications for use are substantially equivalent.

None of these differences, raise any new issues of safety or effectiveness of the new device compared to the predicate device. All respective standards have been applied during compliance testing.

**Overall Discussion and Conclusion:**

The comparison between the predicate device and the subject device of this submission as well as the certified testing conducted for biological safety and electrical safety and the results of the standard testing, bench testing and bench marking demonstrates that the subject device is substantially equivalent to the predicate device.

**Performance Testing/ Standard Testing**

**Electrical Safety**

The Stim2Go device was tested and found to comply with recognized standards for electrical safety. The following tests of the 60601-1 and 60601-2-10 have been performed:

- Power input
- Interruption of the power supply
- Determination of accessible parts
- Legibility of marking
- Durability of marking
- Residual voltage or stored charge in mains plug
- Patient lead connection
- Working voltage measurement
- Leakage current
- Dielectric strength test (MOOP) / (MOPP)
- Measurement of creepage distance and air clearance
- Power or energy dissipation to waive SFC
- Electrical single fault conditions
- Output amplitude control
- Accuracy of pulse parameters
- Compliance after open-circuited and short-circuited electrodes
- Supply voltage fluctuations
- Output interlock
- Output indicator
- Limitation of output parameters

All tests have been caried out at certified test house.

Pass / Fail: PASS

**Battery Safety**

The integrated battery of the Stim2Go device was tested and found to comply with recognized standards for Polymer Li-ion Recharged Batteries safety. The following tests of the IEC 62133-2 have been performed:

- Design recommendation;
- Charging procedure for test purposes (for Cells and Batteries);
- Continuous charging at constant voltage (cells);
- External short circuit (cells);
- External short circuit (batteries);
- Free fall (cells and batteries);
- Thermal abuse (cells);
- Crush (cells);
- Over-charging of battery;
- Forced discharge (cells);
- Mechanical tests (batteries);
- Design evaluation - Forced internal short circuit (cells)

Tests are made with the number of cells and batteries specified in IEC 62133-2: 2017 Table 1. All tests have been caried out at certified test house.

Pass / Fail: PASS

**Mechanical and temperature / climate Safety**

The Stim2Go device was tested and found to comply with recognized standards for mechanical and temperature safety. The following tests of the 60601-1 have been performed:

- Excessive temperatures in ME Equipment
- Operation to a specified temperature
- Humidity preconditioning
- Ingress of water or particulate matter
- Mechanical strength tests
- Mould stress relief test
- Ball pressure test of thermoplastic parts

All tests have been caried out at certified test house.

Pass / Fail: PASS

**Electromagnetic Compatibility**

The Stim2Go device was tested and found to comply with recognized standards for electromagnetic compatibility. The following tests of the 60601-1-2 have been performed:

- Conducted emission
- Radiated RF emission
- Voltage fluctuations and flicker
- Electrostatic discharges
- Radiated RF EM fields
- Proximity fields from RF wireless communications
- equipment
- Electrical fast transients / burst
- Surges
- Conducted disturbances induced by RF fields
- Rated power frequency magnetic fields
- Voltage dips
- Voltage interruptions
- Proximity magnetic fields

All tests have been caried out at certified test house.

Pass / Fail: PASS

**FCC Radio Frequency Testing**

The integrated wireless module of the Stim2Go device was tested to FCC requirements and found to comply with the requirements of 47 CFR 15.247

- Peak Output Power
- 6 dB Bandwidth
- Conducted Spurious Emission and Band Edges
- Maximum Conducted Output Power Density
- Radiated Emission
- Conducted Emission

All tests have been caried out at certified test house.

Pass / Fail: PASS

**Software Verification**

The device's software was verified in accordance with the requirements of FDA's guidance document and the IEC 62304. The software testing demonstrated that the software meets its design requirements.

All tests have been caried out internally. An external test house approved the compliance against IEC 62304.

Pass / Fail: PASS

**Usability/Human Factors Testing:**

Usability/Human Factors testing was performed, which demonstrated that the established requirements for usability were met, and the device's design is appropriate for the intended users and use environment. The result of this study substantiates the acceptability of the use-related risks identified during the risk assessment activities.

A formative and summative usability evaluation have been carried out. An external test house approved the compliance against IEC 60601-1-6.

Pass / Fail: PASS