October 1, 2021

EGZOTech Sp. z o. o.
% Vaibhav Rajal
Official Correspondent for EGZOTech Sp. z o.o.
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K210002
Trade/Device Name: Stella Bio
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, HCC, GZI, KPI
Dated: September 3, 2021
Received: September 3, 2021

Dear Vaibhav Rajal:

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,

Patrick Antkowiak, PhD
Assistant Director (Acting)
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210002

Device Name
STELLA BIO

Indications for Use *(Describe)*
For Prescription and Home Use by prescription from a medical professional:

The Stella BIO is a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions

As a powered muscle stimulator, Stella BIO is indicated for the following conditions:
- Relaxation of muscle spasms,
- Prevention or retardation of disuse atrophy,
- Increasing local blood circulation,
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
- Maintaining or increasing range of motion,
- Muscle re-education.

As a transcutaneous electrical nerve stimulator for pain relief, Stella BIO 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, Stella BIO is indicated for:
- Biofeedback, relaxation and muscle re-education.

As an external functional neuromuscular stimulator, Stella BIO is indicated for the following conditions:
- Helps to relearn voluntary motor functions of the extremities.

As a non-implanted electrical continence device, Stella BIO is indicated for the following conditions:
- Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles.
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as abdominal and the gluteus muscles.

Patient population: Stella BIO Prescription and Home Use by prescription from a medical professional can be used on adults aged 22 yrs and older.

Environments of Use: Clinics, hospital and home environments.

Platform: Stella BIO is a battery-powered, wireless device, accessible through software.

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

The assigned 510(k) number is: K210002

Submitter's Identification:

Submitter's Name and Address: EGZOTech Sp. Z.o.o.
Romualda Traugutta 6h
44-100 Gliwice, Poland

Contact Person: Dr. Michal Mikulski
Chief Executive Officer

Telephone: +48 32 750 49 45

Email: fda@egzotech.com

Date: October 1, 2021

Name of the Device:

Trade Name: Stella BIO

FDA Product Codes, Common Name, Regulation Description and Regulation Number:

FDA Product Code	Common Name	Regulation Description	Regulation Number
IPF	Stimulator, Muscle, Powered	Powered muscle stimulator	890.5850
GZJ	Stimulator, Nerve, Transcutaneous, For Pain Relief	Transcutaneous electrical nerve stimulator for pain relief.	882.5890
HCC	Device, Biofeedback	Biofeedback device.	882.5050
GZI	Stimulator, Neuromuscular, External Functional	External functional neuromuscular stimulator.	882.5810
KPI	Stimulator, Electrical, Non-Implantable, For Incontinence	Nonimplanted electrical continence device.	876.5320

Information for the 510(k) Cleared Device (Predicate Device):

Predicate Device for Prescription and Home Use by prescription from a medical professional:

510(k) number	Predicate device	Manufacturer	Regulation Number	Product Code	Clearance Date
K080950	Stiwell med4	Otto Bock Healthcare	890.5850	IPF, GZJ,	2009-04-02

		Product GmbH Kaiserstrasse 39 1070 Vienna Austria		HCC, GZI, KPI	

Applicable FDA Product Codes, Common Name, Regulation Description and Regulation Number for the Predicate Device:

FDA Product Code	Common Name	Regulation Description	Regulation Number
IPF	Stimulator, Muscle, Powered	Powered muscle stimulator	890.5850
GZJ	Stimulator, Nerve, Transcutaneous, For Pain Relief	Transcutaneous electrical nerve stimulator for pain relief.	882.5890
HCC	Device, Biofeedback	Biofeedback device.	882.5050
GZI	Stimulator, Neuromuscular, External Functional	External functional neuromuscular stimulator.	882.5810
KPI	Stimulator, Electrical, Non-Implantable, For Incontinence	Nonimplanted electrical continence device.	876.5320

Device Description:

The Stella BIO is a neuromuscular electronic stimulator, non-implantable incontinence device and biofeedback device, designed for stationary use in the clinics and hospitals by the medical professionals as well as in the home environment by the patient.

Stella BIO is a single presentation device (one hardware) with a single software license for Prescription and Home Use by prescription from a medical professional.

For the **Prescription and Home Use by prescription from a medical professional Software License**, the medical professional has the ability to adjust, monitor and progress the therapy. This License comes with two User Manuals:

- User Manual for the medical professionals (including instructions on how to adjust parameters of the programs and prescribe exercises for patients)
- User Manual for the patient (including instruction on how to use programs prescribed and adjusted by the medical professional)

The Stella BIO is a battery-powered, wireless device, accessible through software on a mobile device (PC, tablet or smartphone). Statistics regarding the completed treatment can be retrieved from the PC.

In order to gain a proper understanding of Stella BIO, it is important to read the manual before beginning to use the Stella BIO.

Indications for Use

For Prescription and Home Use by prescription from a medical professional:

The Stella BIO is a neuromuscular electrical stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.

As a **powered muscle stimulator**, Stella BIO is indicated for the following conditions:
• Relaxation of muscle spasms,
• Prevention or retardation of disuse atrophy,
• Increasing local blood circulation,
• Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
• Maintaining or increasing range of motion,
• Muscle re-education.

As a **transcutaneous electrical nerve stimulator for pain relief**, Stella BIO 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**, Stella BIO is indicated for:
• Biofeedback, relaxation, and muscle re- education.

As an **external functional neuromuscular stimulator**, Stella BIO is indicated for the following conditions:
• Helps to relearn voluntary motor functions of the extremities.

As a **non-implanted electrical continence device**, Stella BIO is indicated for the following conditions:
• Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles.
• Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as abdominal and the gluteus muscles.

Patient population: Stella BIO Prescription and Home Use by prescription from a medical professional can be used on adults aged 22 yrs and older.

Environments of Use: Clinics, hospital and home environments.

Platform: Stella BIO is a battery-powered, wireless device, accessible through software.

Comparison to the 510(k) Cleared Devices (Predicate Devices)

Basic Device Characteristics			
Characteristics / Specification	**New Device**	**Predicate**	**Difference**
510(k) Number	K210002	K080950	N/A

Manufacturer	EGZOTech	Otto Bock	N/A
Device Name, Model	Stella BIO	STIWELL med4	N/A
Prescription or OTC	Prescription and Home Use	Prescription	Same
Product codes	IPF, GZJ, HCC, GZI, KPI	IPF, GZJ, HCC, GZI, KPI	Same
Classification	Class II	Class II	Same
Indications For Use Statement	**For Prescription and Home Use by prescription from a medical professional:** The Stella BIO is a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions As a powered muscle stimulator, Stella BIO is indicated for the following conditions: - Relaxation of muscle spasms, - Prevention or retardation of disuse atrophy, - Increasing local blood circulation, - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, - Maintaining or increasing range of motion. - Muscle re-education, As a transcutaneous electrical nerve stimulator for pain relief, Stella BIO 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	**For Prescription:** 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. As a powered muscle stimulator the STIWELL med4 is indicated for the following conditions: - Relaxation of muscle spasms, - Prevention or retardation of disuse atrophy, - Increasing local blood circulation, - Muscle re-education, - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, - Maintaining or increasing range of motion. As a transcutaneous electrical nerve stimulator for pain relief the STIWELL med4 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. As a biofeedback device Stella BIO is indicated for: - Biofeedback, relaxation and muscle re- education purposes. As an external functional neuromuscular stimulator Stella BIO is indicated for the following conditions: - Helps to relearn voluntary motor functions of the extremities. As a non-implanted electrical continence device, Stella BIO is indicated for the following conditions: - Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles. - Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as abdominal and the gluteus muscles. **Patient population:** Stella BIO Prescription and Home Use by prescription from a medical professional can be used on adults aged 22 yrs and older. **Environments of Use:** Clinics, hospital and home environments. **Platform:** Stella BIO is a battery-powered, wireless device, accessible through software.	pain and post traumatic acute pain. As a biofeedback device the STIWELL med4 is indicated for: - Biofeedback, relaxation and muscle re- education purposes. As an external functional neuromuscular stimulator the STIWELL med4 is indicated for the following conditions: - Helps to relearn voluntary motor functions of the extremities. As a non-implanted electrical continence device the STIWELL med4 is indicated for the following conditions: - Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles. - Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as abdominal and the gluteus muscles.	

Environment of Use	Clinics, hospital and home environments	Clinics, hospital and home environments	Same
Patient population	Adults 22 yrs and older	Adults	Same
Power Source	Battery Pack Li-Ion 7,4 V	Battery Pack Li-Ion 11,1 V	Different Note 1
Method of Line Current Isolation	N/A (Battery)	Medical Class II Power Adapter - Mascot (12,6VDC-15,1W)	Different Note 1
Patient Leakage Current (normal condition, µA)	N/A Battery Operated Device (<100µA patient leakage)	N/A Battery Operated Device (<100µA patient leakage)	Same
Patient Leakage Current (single fault condition)	N/A Battery Operated Device (<100µA patient leakage)	N/A Battery Operated Device (<100µA patient leakage)	Same
Number of Output Modes	4 (EMS, TENS, Biofeedback, Incontinence)	1	Different Note 2
Software/ Firmware/ Microprocessor control	YES	YES	Same
Automatic Overload Trip	YES	YES	Same
Automatic No-Load Trip	YES	YES	Same
Automatic Shut Off	YES (10 min)	YES (10 min)	Same
Patient Override Control	YES (Button)	YES (Stop Button)	Same
Indicator Display: On/Off Status	YES	YES	Same
Indicator Display: Low Battery	YES	YES	Same

Indicator Display: Voltage/Current Level	YES	YES	Same
Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11 IEC 62304 IEC 62366 IEC 62133 ANSI/AAMI NS4	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Different Note 3
Compliance with 21 CFR 898	YES	YES	Same
Weight	112 g	440 g	SE Note 4
Dimension (WxHxL) in [mm]	91.5 x 68.4 x 24 mm	175 x 95 x 30 mm	SE Note 4
Housing material and Construction	Plastic (Injection Molded ABS)	Plastic (Injection Molded ABS)	Same

Substantial Equivalence discussion and Differences analysis for Basic Device Characteristics - Comparison with the predicate Device:

- **Note 1 : "Power Source" and "Method of Line Current isolation"**
  The predicate device as well as the subject device are battery powered. Although the battery provided by the new device is different from the battery of the predicate device, it is compliant with IEC 62133 standard. Moreover, the new device is IEC 60601-1 compliant and has been tested for electrical safety with a positive result. Because the new device is battery powered it doesn't require methods of line current isolation and patient leakage current is not applicable. Therefore differences in power source doesn't influence essential performance or basic safety, as well as doesn't impact substantial equivalence to the predicate device.

- **Note 2: "Number of Output Modes"**
  Although the "Number of Output Modes" is different from the predicate device they all comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn't impact essential performance, basic safety or substantial equivalence.

- **Note 3: "Voluntary Standards"**
  The new device complies with the same voluntary standards as the predicate device as well as additional standard ANSI/AAMI NS4. All voluntary standards are recognized FDA standards and this change difference doesn't impact essential performance, basic safety or substantial equivalence.

- **Note 4: Weight" and "Dimensions"**
  Although "Weight" and "Dimensions" of subject device are different from the predicate device, they all comply with IEC 60601-1, IEC 60601-2-10 and IEC 60601-1-11 requirements, thus the differences of the function specifications does not raise any safety or effectiveness issue.

Powered Muscle Stimulator Designation Comparison of Proposed New Device and Predicate Device

Powered Muscle Stimulator			
Characteristics/ Specifications	**New Device**	**Predicate**	**Differences:**
510(k) Number	K210002	K0809050	N/A
Manufacturer	EGZOTech	Otto Bock	N/A
Device Name, Model	Stella BIO	STIWELL med4	N/A
Treatment Time Range [min]	1 - 60 min	2 - 120 min	Different Note 1 PMS
Number of Output Channels	Up to 8	4	Different Note 2 PMS
EMG Specifications			
Number of EMG Channels	Up to 8	Up to 4	Different Note EMG
EMG sensitivity	0.5 µV	1 µV	Different Note EMG
EMG detection (bipolar/monopolar)	Bipolar	Bipolar	Same
EMG Sampling Rate	Up to 4 kHz	3 kHz	Different Note EMG
EMG range (µV)	± 6 000 µV	1 - 2000 µV	Different Note EMG
EMG bandwidth	0 - 2 kHz pre-filtering 20 - 100 Hz post	70-480 Hz	Different Note EMG

EMG signal processing (e.g. RMS)	RMS (Root Mean Square)	AVR (Average Retched Value)	Different Note EMG
Synchronous or Alternating	Synchronous	Alternating	Different Note EMG
Method of Channel Isolation	Multiplexer	Transformer, Inductive couplers	Different Note EMG
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Same
Output Specifications			
Waveform	Biphasic symmetrical	Biphasic symmetrical	Same
Shape	Rectangular, triangular, trapezoidal, sinusoidal	Rectangular	Different Note 3 PMS
Maximum Output Voltage (500Ω)	50 V	50 V	Different Note 4 PMS
Maximum Output Voltage (2kΩ)	60 V	115 V	Different Note 4 PMS
Maximum Output Voltage (10kΩ)	N/A	N/A	Different Note 4 PMS
Maximum Output Current (500Ω)	100 mA	100 mA	Different Note 4 PMS
Maximum Output Current (2kΩ)	30 mA	50 mA	Different Note 4 PMS
Maximum Output Current (10kΩ)	N/A	N/A	Different Note 4 PMS
Pulse Width (specialty units)	50 µs - 400 µs	50 µs - 400 µs	Same
Frequency (Hz)	1 Hz - 140 Hz	1 - 140 Hz	Same
For interferential	N/A	N/A	Same

modes only: Beat Frequency (Hz)			
For multiphasic waveforms only: Symmetrical phases?	N/A	N/A	Same
For multiphasic waveforms only: Phase Duration (including units)	N/A	N/A	Same
Net Charge [µC per pulse] (500Ω)	0 µC Same positive and negative impulse	0 µC Same positive and negative impulse	Same
Maximum Phase Charge [µC] (500Ω)	40 µC	40 µC	Same
Maximum Current Density [mA/cm2] (500Ω)	0.22 mA/cm2	12,5 mA/cm2	Different Note 5 PMS
Maximum Power Density [W/cm2] (500Ω)	0.63 mW/cm2	7,9m W/cm2	Different Note 5 PMS
On Time [seconds]	1 - 10 s	1 - 20 s	Different Note 6 PMS
Off Time [seconds]	1 - 60 s	1 - 50 s	Different Note 6 PMS

Substantial Equivalence discussion and Differences Analysis - Output Specifications for Powered Muscle Stimulator - Comparison with Predicate Device

Note 1 PMS: "Treatment Time range"
Although the "Treatment Time range" in the new device is different from the time range in predicate device, it complies with IEC 60601-1 and IEC 60601-2-10 requirements and doesn't impact essential performance, basic safety or substantial equivalence.

Note 2 PMS: "Number of Output Channels"
Although the "Number of Output Channels" are different from the predicate device they all comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn't impact essential performance, basic safety or substantial equivalence.

Note EMG:

“EMG Specifications”
The new device as well as the predicate device provide similar EMG- triggered EMS programs that enable the new device to bridge muscle stimulation with patient-initiated muscle contractions to achieve the same unchanged indications for use under 21 CFR 890.5850.

“EMG sensitivity”, “EMG sampling rate” and ”EMG range”
The new device has an improved EMG sensitivity and sample rate compared to the predicate K080950. This can be considered an improvement and difference doesn’t impact essential performance, basic safety or substantial equivalence. The difference in EMG range between the new device and predicate K080950 results from the difference in analog-to-digital converters and voltage references used for both devices. As the new device has a higher maximal EMG range, it can be considered an improvement and difference does not impact essential performance, basic safety or substantial equivalence.

“EMG bandwidth”
The difference in EMG bandwidth results in the difference in filtering methods for both devices - digital for the new device and analog for the predicate K080950. The difference doesn’t impact essential performance, basic safety or substantial equivalence.

“EMG Signal processing”
Additionally, the new device has a different signal processing algorithm - RMS (Root Mean Square) in comparison to AVR (Average Retched Value) for the predicate K080950. Both methods yield comparable results and are industrial standards. Therefore, difference doesn’t impact essential performance, basic safety or substantial equivalence.

“Alternating or Synchronous”
The new device has a Synchronous EMG acquisition triggering. That is an improvement over Alternating EMG acquisition in predicate device K080950, as the EMG samples can be acquired and compared sample-to-sample, which in Alternating sampling is not possible. This can be considered an improvement and difference doesn’t impact essential performance, basic safety or substantial equivalence.

Note 3 PMS: “Shape of the waveforms“
Predicate device provide only biphasic rectangular waveforms. The new device provides additional waveforms shapes (triangular, trapezoidal and sinusoidal) in addition to rectangular waveforms. Electrical stimulation for triangular, trapezoidal and sinusoidal waveforms are safer than rectangular waveforms due to lower maximal phase charge, current density and power density. Additionally, electrical stimulation for all waveforms were tested and are compliant with the requirements in IEC 60601-2-10. The difference in waveforms doesn’t impact essential performance, basic safety or substantial equivalence.

Note 4 PMS: “Maximum Output Voltage” and “Maximum Output Current”
Although the “Maximum Output Voltage” and “Maximum Output Current” of the new device are different than in the predicate device, they were all tested and are compliant with IEC 60601-2-10. Therefore the difference doesn’t impact essential performance, basic safety or substantial equivalence.

Note 5 PMS: “Maximum Current Density” and “Maximum Power Density”
The “Maximum Current Density” and “Maximum Power Density” of the new device is lower than in the predicate device K080950 and doesn’t impact essential performance, basic safety or substantial equivalence. The Maximum Power density for the new device is 0.63 mW/cm2 vs. 7.9 mW/cm2 in the predicate K080950. This is especially related to the electrodes used in both devices which are different. The Maximum Power density for the new device is less than 0.25 Watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns and The Maximum Current Density for all waveforms of the new device is compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s, thus the difference doesn’t impact essential performance, basic safety or substantial equivalence.

Note 6 PMS: “On/Off time”
Although “on and off time” are slightly different, the new device is compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s and the difference will not raise any safety or effectiveness issue. The subject device and the predicate device have the technical specifications that are within a range of other FDA cleared powered muscle stimulators.

Functional Electrical Stimulation Designation Comparison of Proposed New Device and Predicate Device

Functional Electrical Stimulation (FES)			
Characteristics/ Specifications	**New Device**	**Predicate Device**	**Differences :**
510(k) Number	K210002	K0809050	N/A
Manufacturer	EGZOTech	Otto Bock	N/A
Device Name, Model	Stella BIO	STIWELL med4	N/A
Time Range [minutes]	15 - 60 min	15 - 60 min	Same
EMG Specifications			
Number of EMG Channels	Up to 8	Up to 4	Different Note EMG
EMG sensitivity	0.5 µV	1 µV	Different Note EMG
EMG detection (bipolar/monopolar)	Bipolar	Bipolar	Same

EMG Sampling Rate	Up to 4 kHz	3 kHz	Different Note_EMG
EMG range (µV)	± 6 000 µV	1 - 2000 µV	Different Note_EMG
EMG bandwidth	0 - 2 kHz pre-filtering 20 - 100 Hz post	70-480 Hz	Different Note_EMG
EMG signal processing (e.g. RMS)	RMS (Root Mean Square)	AVR (Average Retched Value)	Different Note_EMG
Synchronous or Alternating	Synchronous	Alternating	Different Note_EMG
Method of Channel Isolation	Multiplexer	Transformer, Inductive couplers	Different Note_EMG
Output Specifications			
Waveform	Biphasic symmetrical	Biphasic symmetrical	Same
Shape	Rectangular	Rectangular	Same
Maximum Output Voltage (500Ω)	50 V	50 V	Same
Maximum Output Voltage (2kΩ)	60 V	115 V	Different Note 1 FES
Maximum Output Voltage (10kΩ)	N/A	N/A	Same
Maximum Output Current (500Ω)	100 mA	100 mA	Same
Maximum Output Current (2kΩ	30 mA	58 mA	Different Note 1 FES
Maximum Output Current (10kΩ)	N/A	N/A	Same
Pulse Width (specialty units)	50 µs - 400 µs	50 µs - 400 µs	Same
Frequency (Hz)	1 - 140 Hz Default: 35 Hz	1 - 140 Hz Default: 35 Hz	Same
Net Charge [µC per pulse] (500Ω)	0µC Same positive and negative impulse	0µC Same positive and negative impulse	Same

Maximum Phase Charge [µC] (500Ω)	40 µC	40 µC	Same
Maximum Current Density [mA/cm2] (500Ω)	0.22 mA/cm2	12,5 mA/cm2	Different Note 2 FES
Maximum Power Density [W/cm2] (500Ω)	0.63 mW/cm2	7,9 mW/cm2	Different Note 2 FES
On Time [seconds]	1 - 20 s	1 - 20 s	Same
Off Time [seconds]	1 - 30s or Trigger controlled (min. 1 - 30 s)	1 - 30s or Trigger controlled (min. 1 - 30 s)	Same

Substantial Equivalence discussion and Differences Analysis - Output Specifications for Functional Electrical Stimulation - Comparison with Predicate Device

Note EMG:

"EMG Specifications"
The new device as well as the predicate device provide similar EMG- triggered EMS programs that enable the new device to bridge muscle stimulation with patient-initiated muscle contractions to achieve the same unchanged indications for use under 21 CFR 890.5850.

"EMG sensitivity", "EMG sampling rate" and "EMG range"
The new device has an improved EMG sensitivity and sample rate compared to the predicate K080950. This can be considered an improvement and difference doesn't impact essential performance, basic safety or substantial equivalence. The difference in EMG range between the new device and predicate K080950 results from the difference in analog-to-digital converters and voltage references used for both devices. As the new device has a higher maximal EMG range, it can be considered an improvement and difference doesn't impact essential performance, basic safety or substantial equivalence.

"EMG bandwidth"
The difference in EMG bandwidth results in the difference in filtering methods for both devices - digital for the new device and analog for the predicate K080950. The difference doesn't impact essential performance, basic safety or substantial equivalence.

"EMG Signal processing"
Additionally, the new device has a different signal processing algorithm - RMS (Root Mean Square) in comparison to AVR (Average Retched Value) for the predicate K080950. Both methods yield comparable results and are industrial standards. Therefore difference doesn't impact essential performance, basic safety or substantial equivalence.

“Alternating or Synchronous”
The new device has a Synchronous EMG acquisition triggering. That is an improvement over Alternating EMG acquisition in predicate device K080950, as the EMG samples can be acquired and compared sample-to-sample, which in Alternating sampling is not possible. This can be considered an improvement and difference doesn’t impact essential performance, basic safety or substantial equivalence.

Note 1 FES: “Maximum Output Voltage” , “Maximum Output Current”.
Although the “Maximum Output Voltage” and “Maximum Output Current” at 2kΩ of the new device are different than in the predicate device, they are all compliant and tested with IEC 60601-2-10. Therefore the difference doesn’t impact essential performance, basic safety or substantial equivalence.

Note 2 FES: “Maximum Current Density” and “Maximum Power Density”
Although the “Maximum Current Density” and “Maximum Power Density” of subject device are different from the predicate device, which is related to the electrode surface that is different for both devices, they all comply with the FDA guidance requirement for Powered Muscle Stimulator 510 (k)s, so the differences of function specification will not raise any safety or effectiveness issue.

Transcutaneous Electrical Nerve Stimulation Designation Comparison of Proposed New Device and Predicate Device

Transcutaneous Electrical Nerve Stimulation (TENS)			
Characteristics/ Specifications	**New Device**	**Predicate Device**	**Differences:**
510(k) Number	K210002	K0809050	-
Manufacturer	EGZOTech	Otto Bock	-
Device Name, Model	Stella BIO	STIWELL med4	-
Treatment Time Range [minutes]	10 - 120 min	10 - 120 min	Same
Output Specification			
Waveform	Biphasic symmetrical	Biphasic symmetrical	Same
Shape	Rectangular	Rectangular	Same
Maximum Output Voltage (500Ω)	50 V	50 V	Same
Maximum Output Voltage (2kΩ)	60 V	115 V	Different Note 1

			TENS
Maximum Output Voltage (10kΩ)	N/A	N/A	Same
Maximum Output Current (500Ω)	100 mA	100 mA	Same
Maximum Output Current (2kΩ)	30 mA	58 mA	Different Note 1 TENS
Maximum Output Current (10kΩ)	N/A	N/A	Same
Pulse Width (specialty units)	150 µs - 200 µs	150 µs - 200 µs	Same
Frequency (Hz)	2 Hz - 100 Hz	2 Hz -100 Hz	Same
For interferential modes only: Beat Frequency (Hz)	N/A	N/A	Same
For multiphasic waveforms only: Symmetrical phases	N/A	N/A	Same
For multiphasic waveforms only: Phase Duration (including units)	N/A	N/A	Same
Net Charge [µC per pulse] (500Ω)	0 µC Same positive and negative impulse	0 µC Same positive and negative impulse	Same
Maximum Phase Charge [µC] (500Ω)	20 µC	20 µC	Same
Maximum Current Density [mA/cm2] (500Ω)	0.15 mA/cm2	12.5 mA/cm2	Different Note 2 TENS
Maximum Power Density [W/cm2] (500Ω)	0.28 mW/cm2	1,0 mW/cm2	Different Note 2 TENS
Burst Mode: Pulse per burst	8	8	Same

Burst Mode: Bursts per second	2	2	Same
Burst Mode: Burst duration (seconds)	100 ms	100 ms	Same
Burst Mode: Duty Cycle	20 %	20 %	Same
On Time [seconds]	Continuous or Burst	Continuous or Burst	Same
Off Time [seconds]	N/A	N/A	Same

Substantial Equivalence discussion and Differences Analysis - Output Specifications for TENS – Comparison with Predicate Device

Note 1 TENS: "Maximum Output Voltage" , "Maximum Output Current".
Although the "Maximum Output Voltage" and "Maximum Output Current" at 2kΩ of the new device are different from in the predicate device, they are all compliant and tested with IEC 60601-2-10. Therefore, the difference doesn't impact essential performance, basic safety or substantial equivalence.

Note 2 TENS: "Maximum Current Density" and "Maximum Power density"
The Maximum Current Density and Maximum Power Density of the new device is lower than in the predicate device. This is especially related to the electrodes used in the predicate device, which are different. The Maximum Power density for the new device is less than 0.25 watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns. The Maximum Current Density is compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s and the difference doesn't impact essential equivalence.

Incontinence Programs Designation Comparison of Proposed New Device and Predicate Device

Incontinence Programs			
	New Device	**Predicate Device**	**Differences**
510(k) Number	K210002	K080950	N/A
Manufacturer	EGZOTech	Otto Bock	N/A
Device Name, Model	Stella BIO	STIWELL med4	N/A
Treatment Time Range [minutes]	0 - 60 min	2 - 25 min	Different Note 1 KPI

EMG Specifications			
Number of EMG Channels	Up to 8	Up to 4	Different Note_EMG
EMG sensitivity	0.5 µV	1 µV	Different Note_EMG
EMG detection (bipolar/monopolar)	Bipolar	Bipolar	Same
EMG Sampling Rate	Up to 4 kHz	3 kHz	Different Note_EMG
EMG range (µV)	± 6 000 µV	1 - 2000 µV	Different Note_EMG
EMG bandwidth	0 - 2 kHz pre-filtering 20 - 100 Hz post	70-480 Hz	Different Note_EMG
EMG signal processing (e.g.RMS)	RMS (Root Mean Square)	AVR (Average Retched Value)	Different Note_EMG
Synchronous or Alternating	Synchronous	Alternating	Different Note_EMG
Method of Channel Isolation	Multiplexer	Transformer, Inductive couplers	Different Note_EMG
Output Specifications			
Waveform	Biphasic symmetrical	Biphasic symmetrical	Same
Shape	Rectangular	Rectangular	Same
Maximum Output Voltage (500Ω)	50V	50V	Same
Maximum Output Voltage (2kΩ)	60V	115V	Different Note 2 KPI
Maximum Output Voltage (10kΩ)	N/A	N/A	Same
Maximum Output Current (500Ω)	100mA	100mA	Same
Maximum Output Current (2kΩ)	30mA	58mA	Different Note 2 KPI

Maximum Output Current (10kΩ)	N/A	N/A	Same
Pulse Width (specialty units)	150 µs - 250 µs program dependent	300 - 500 µs program dependent	Different Note 3 KPI
Frequency (Hz)	0 - 50 Hz program dependent	5 - 60 Hz program dependent	Different Note 3 KPI
Net Charge [µC per pulse] (500Ω)	0µC Same positive and negative impulse	0µC Same positive and negative impulse	Same
Maximum Phase Charge [µC] (500Ω)	25 µC	50 µC	Different Note 4 KPI
Maximum Current Density [mA/cm2] (500Ω)	0.65 mA/cm2 Surface = 1.93 cm2 For the smallest electrode surface area	4.7mA/cm2 Surface = 21.2cm2	Different Note 4 KPI
Maximum Power Density [W/cm2] (500Ω)	0.40 mW/cm2 At maximum frequency of 50Hz pulse width 250µS and current of 100mA. Smallest Electrode area (PR - 06A) : 1.93 cm2	0.42 - 105 mW/cm2 Surface = 21,2 cm2	Different Note 4 KPI
On Time [seconds]	1 - 6 s	9 - 13 s	Different Note 5 KPI
Off Time [seconds]	0 - 12 s	3 - 9 s	Different Note 5 KPI

Substantial Equivalence discussion and Differences Analysis - Output Specifications for Incontinence Programs - Comparison with Predicate Device

Note 1 KPI: "Treatment Time range"
The incontinence programs of the new device have a pre-set time range between 15 - 20 min (program dependent), similar to predicate. The new device has one additional "Custom Program" where time range can be adjusted by a medical professional in the range of 1-60 min. Although the "Treatment Time range" in the new device is slightly different from the time range in predicate device K080950 it complies with IEC 60601-1 and IEC 60601-2-10 requirements and doesn't impact essential performance, basic safety or substantial equivalence.

Note EMG:

“EMG Specifications”
The new device as well as the predicate device provide similar EMG- triggered EMS programs that enable the new device to bridge muscle stimulation with patient-initiated muscle contractions to achieve the same unchanged indications for use under 21 CFR 890.5850.

“EMG sensitivity”, “EMG sampling rate” and ”EMG range”
The new device has an improved EMG sensitivity and sample rate compared to the predicate K080950. This can be considered an improvement and difference doesn’t impact essential performance, basic safety or substantial equivalence. The difference in EMG range between the new device and predicate K080950 results from the difference in analog-to-digital converters and voltage references used for both devices. As the new device has a higher maximal EMG range, it can be considered an improvement and difference doesn’t impact essential performance, basic safety or substantial equivalence.

“EMG bandwidth”
The difference in EMG bandwidth results in the difference in filtering methods for both devices - digital for the new device and analog for the predicate K080950. The difference doesn’t impact essential performance, basic safety or substantial equivalence.

“EMG Signal processing”
Additionally, the new device has a different signal processing algorithm - RMS (Root Mean Square) in comparison to AVR (Average Retched Value) for the predicate K080950. Both methods yield comparable results and are industrial standards. Therefore, difference doesn’t impact essential performance, basic safety or substantial equivalence.

“Alternating or Synchronous”
The new device has a Synchronous EMG acquisition triggering. That is an improvement over Alternating EMG acquisition in predicate device K080950, as the EMG samples can be acquired and compared sample-to-sample, which in Alternating sampling is not possible. This can be considered an improvement and difference does not impact essential performance, basic safety or substantial equivalence.

Note 2 KPI: “Maximum Output Voltage” , “Maximum Output Current”.
Although the “Maximum Output Voltage” and “Maximum Output Current” at 2kΩ of the new device are different than in the predicate device, they are all compliant and tested with IEC 60601-2-10. Therefore the difference doesn’t impact essential performance, basic safety or substantial equivalence.

Note 3 KPI: “Pulse width modulation” and “Frequency”
The new device has slightly different pulse widths (150 µs - 250 µs in the new device) vs 300 µs - 500 µs in the predicate device K080950. Although the “pulse width” is different from the predicate device, it is within the range of the standard EMS pulse modulation that is compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s, so the differences of function specification will not raise any safety or effectiveness issue.

The frequency for the new device is 0 - 50 Hz and is similar to the predicate K0809050 (5-60 Hz). This difference does not raise new types of safety or effectiveness questions because all devices are using standard EMS stimulation frequencies that are compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s. Maximum pulse frequency of the new device was tested and is compliant with IEC 60601-2-10.

Note 4 KPI: "Maximum Phase charge", "Maximum Current Density", "Maximum Power Density"
The "Maximum phase charge of the new device is 25 µC for the new device and is different from the predicate K080950 (50 µC). This difference does not raise new types of safety or effectiveness questions because all devices are compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s and were tested and are compliant with IEC 60601-2-10.

The "Maximum Current Density" and "Maximum Power Density" are different than in the predicate device. This is especially related to the electrodes used in the predicate device which are different. The maximum power density for the smallest surface electrode used in the new device is lower than in the predicate (0.40 mW/cm2 in the new device vs. 105 mW/cm2 in the predicate K080950). Moreover, the Maximum Power Density for the smallest electrode used in the device is less than 0.25 Watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns. The Maximum Current Density and Maximum Power Density of the new device is compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s, thus the difference doesn't impact essential performance, basic safety or substantial equivalence.

Note 5 KPI: "On/Off time"
Although the "on/off" time is slightly different for both devices it is compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s and the difference between on and off time ranges doesn't impact essential performance, basic safety or substantial equivalence.

Biofeedback Designation Comparison of Proposed New Device and Predicate Device

Biofeedback			
Characteristics/ Specifications	**New Device**	**Predicate Device**	**Differences**
510(k) Number	K210002	K080950	N/A
Manufacturer	EGZOTech	Otto Bock	N/A
Device Name, Model	Stella BIO	STIWELL med4	N/A
Time Range [minutes]	5- 20 min Default 10 min	5 - 30 min	Different Note 1 HCC
EMG Specifications			

Number of EMG Channels	Up to 8	Up to 4	Different Note EMG
EMG sensitivity	0.5 µV	1 µV	Different Note EMG
EMG detection (bipolar/monopolar)	Bipolar	Bipolar	Same
EMG Sampling Rate	Up to 4 kHz	3 kHz	Different Note EMG
EMG range (µV)	± 6 000 µV	1 - 2000 µV	Different Note EMG
EMG bandwidth	0 - 2 kHz pre-filtering 20 - 100 Hz post	70-480 Hz	Different Note EMG
EMG signal processing (e.g.RMS)	RMS (Root Mean Square)	AVR (Average Retched Value)	Different Note EMG
Synchronous or Alternating	Synchronous	Alternating	Different Note EMG
Method of Channel Isolation	Multiplexer	Transformer, Inductive couplers	Different Note EMG
Output Specification for Biofeedback			
Waveform	Not applicable	Not applicable	Same
Shape	Not applicable	Not applicable	Same
Maximum Output Voltage (500Ω)	Not applicable	Not applicable	Same
Maximum Output Voltage(2kΩ)	Not applicable	Not applicable	Same
Maximum Output Voltage (10kΩ)	Not applicable	Not applicable	Same
Maximum Output Current (500Ω)	Not applicable	Not applicable	Same
Maximum Output Current (2kΩ)	Not applicable	Not applicable	Same
Maximum Output Current (10kΩ)	Not applicable	Not applicable	Same

Pulse Width (specialty units)	Not applicable	Not applicable	Same
Frequency (Hz)	Not applicable	Not applicable	Same
Net Charge [µC per pulse] (500Ω)	Not applicable	Not applicable	Same
Maximum Phase Charge [µC] (500Ω)	Not applicable	Not applicable	Same
Surface area of the electrodes	Not applicable	Not applicable	Same
Maximum Current Density [mA/cm2] (500Ω)	Not applicable	Not applicable	Same
Maximum Power Density [W/cm2] (500Ω)	Not applicable	Not applicable	Same
On Time [seconds]	Not applicable	Not applicable	Same
Off Time [seconds]	Not applicable	Not applicable	Same
Additional features	Not applicable	Not applicable	Same

Substantial Equivalence discussion and Differences Analysis - Output Specifications for EMG Biofeedback - Comparison with Predicate Device

Note 1 HCC: "Treatment Time range"
Although the "Time range" in the new device is different from the time range in predicate device K080950, it complies with IEC 60601-1 and IEC 60601-2-10 requirements and doesn't impact essential performance, basic safety or substantial equivalence.

Note EMG:

"EMG Specifications"
The new device as well as the predicate device provide similar EMG- triggered EMS programs that enable the new device to bridge muscle stimulation with patient-initiated muscle contractions to achieve the same unchanged indications for use under 21 CFR 890.5850.

"EMG sensitivity", "EMG sampling rate" and "EMG range"
The new device has an improved EMG sensitivity and sample rate compared to the predicate K080950. This can be considered an improvement and difference doesn't impact essential performance, basic safety or substantial equivalence. The difference in EMG range between the new device and predicate K080950 results from the difference in analog-to-digital converters and voltage

references used for both devices. As the new device has a higher maximal EMG range, it can be considered an improvement and difference doesn't impact essential performance, basic safety or substantial equivalence.

"EMG bandwidth"
The difference in EMG bandwidth results in the difference in filtering methods for both devices - digital for the new device and analog for the predicate K080950. The difference doesn't impact essential performance, basic safety or substantial equivalence.

"EMG Signal processing"
Additionally, the new device has a different signal processing algorithm - RMS (Root Mean Square) in comparison to AVR (Average Retched Value) for the predicate K080950. Both methods yield comparable results and are industrial standards. Therefore difference doesn't impact essential performance, basic safety or substantial equivalence.

"Alternating or Synchronous"
The new device has a Synchronous EMG acquisition triggering. That is an improvement over Alternating EMG acquisition in predicate device K080950, as the EMG samples can be acquired and compared sample-to-sample, which in Alternating sampling is not possible. This can be considered an improvement and difference doesn't impact essential performance, basic safety or substantial equivalence.

Conclusion: Stiwell med4 was chosen as predicate to the subject device due to the intended use, indications, performance, as well as the function and device testing specification that had been performed. Minor variations between the subject and the predicate device were found and listed within the above discussion. Considerable amount of testing, including electrical safety, electronic compatibility, software validation and verification and usability testing were performed to support the claims of appropriately chosen predicate device.

In accordance with 21 CFR Part 807 and based on the data provided through Substantial Equivalence Discussion it is stated that Stella BIO Device is substantially equivalent as the predicate device Stiwell med4 Powered Muscle Stimulator.

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Stella BIO device in the intended environment of use is supported by testing that was conducted in accordance with the FDA June 1999 Draft "Guidance Document for Powered Muscle Stimulator 510(k)s", CDRH, which outlines Technological Characteristics, Electrode Lead Wires and Patient cables performance standards and Electromagnetic Compatibility (EMC) requirements.

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate device:

Electrical safety and electromagnetic compatibility (EMC)

- IEC 60601-1 — Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 — Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances – Requirements and tests.
- IEC 60601-2-10 — Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
- IEC 60601-1-11 — Medical electrical equipment–Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 62133-2 — Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.
- ANSI/AAMI NS4 — Transcutaneous Electrical Nerve Stimulators

Wi-Fi and Bluetooth testing

The device contains a wireless module with FCC ID: 2AC7Z-ESP WROOM 32 that has been tested and complies with:

- FCC CFR47 Part 15C (2017) Radio Frequency Devices

Software

- IEC 62304 — Medical device software — Software life cycle processes.

Usability

- IEC 62366 — Applying Human Factors and Usability Engineering to Medical Device.

Risk analysis

- ISO 14971 — Medical devices - Application of risk management to medical devices.

Biocompatibility

- ISO 10993-1 — Biological Evaluation of Medical Devices − Part 1: “Evaluation and Testing Within a Risk Management Process”. As dictated by the application and duration of contact with the intact skin, the device testing included the Cytotoxicity, Sensitization and Irritation.

Quality

- ISO 13485 Quality management System

Additional standards

- IEC 62353 Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
- EN 1041 Information supplied by the manufacturer of medical devices
- ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
- 93/42/EEC Annex II Medical Devices Directive, CE Marking for Europe.

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Stella BIO tested met all relevant requirements of the aforementioned tests.

Software information:

Software verification and validation testing were conducted and supported by documentation according to the FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The details of the software license for Prescription and Home Use by prescription from a medical professional software license were clearly demonstrated in the software documentation and the risks related to the software products were mitigated. The software for this device was considered as a "Moderate" level of concern. The proposed subject device is in compliance with IEC 62304 test standard requirements

Conclusions:

Stella BIO is a single device (one hardware) with a single software license for Prescription and Home Use by prescription from a medical professional. The intended use of the Stella BIO device is equivalent with those of the referenced Predicate device for prescription and home use by prescription from a medical professional K080950. The basic technological characteristics are mostly the same for both software licenses of subject and predicate devices with small differences which doesn't raise any safety or effectiveness issues. Comparing the hardware and the software of the subject device it is equivalent to the above mentioned predicate device.

The Stella BIO device complies with the requirement of IEC 60601-1, IEC 60601-2-10, IEC60601-1-2, IEC 60601-1-11 and ANSI/AAMI NS4. The bench testing and safety report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Stella BIO device is substantially equivalent to the predicate device K080950.