December 28, 2023

Evolution Devices, Inc.
Pierluigi Mantovani
CEO
1111 Broadway FL 3,
Oakland, California 94607

Re: K230997
Trade/Device Name: EvoWalk 1.0 System
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: December 5, 2023
Received: December 18, 2023

Dear Pierluigi Mantovani:

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,

Lauren E. Woodard -S

for Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices

OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K230997

Device Name
EvoWalk 1.0 System

Indications for Use *(Describe)*
The EvoWalk 1.0 System is intended to provide ankle dorsiflexion in adult individuals with foot drop and/or to assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The EvoWalk 1.0 System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

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

Evolution Devices, Inc.
EvoWalk 1.0 System

510(k) Summary: EvoWalk 1.0 System

Company Name: Evolution Devices, Inc.

Contact Person:
Pierluigi Mantovani
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Evolution Devices, Inc.
1111 Broadway FL 3, Oakland CA 94607 United States
Phone Number: 6619930685
Email: pierluigi@evolutiondevices.com

Date Prepared: November 15, 2023

Trade Name: EvoWalk 1.0 System

Classification:
Name: External functional neuromuscular stimulator
Product Code: GZI
Regulation Number: 21 CFR 882.5810 External functional neuromuscular stimulator
Class: II
Classification Panel: Neurology

Predicate devices:
Company: Bioness Inc.
Device: L300 Go System (**K173682**)

Purpose of the traditional 510(k): This Traditional 510(k) is submitted to clear a new device, the EvoWalk 1.0 System.

Device description:
The EvoWalk 1.0 system is a wearable non-invasive functional electrical stimulation (FES) device intended to provide ankle dorsiflexion in adult individuals with foot drop and/or to assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways in the spinal cord), thus providing treatment for foot drop. EvoWalk 1.0 can be used in a healthcare facility and home settings.

The EvoWalk 1.0 system consists of the EvoWalk device with an elastic band and built-in rechargeable lithium polymer battery, and the accessories including the EvoWalk mobile application, micro USB type charge cable with charge port, lead cables (one single channel and one dual channel), eight sets of electrodes for each channel, instructions for use (IFU), and a carrying case.

Indications for use:
The EvoWalk 1.0 system is intended to provide ankle dorsiflexion in adult individuals with foot drop and/or to assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron

disease/injury (e.g., stroke, damage to pathways to the spinal cord). The EvoWalk 1.0 system electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

Substantial Equivalence:

Table 1. Predicate Comparison Chart

Trade Name	**EvoWalk 1.0 System (K230997)**	**L300 Go System (K173682)**
Manufacturer	Evolution Devices Inc.	Bioness Inc.
510(k) Number	K230997	K173682
Product Code	GZI	GZI & IPF
Indication for Use	The EvoWalk 1.0 system is intended to provide ankle dorsiflexion in adult individuals with foot drop and/or to assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The EvoWalk 1.0 system electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.	The L300 Go System is intended to provide ankle dorsiflexion in adult and pediatric individuals with foot drop and/or to assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The L300 Go System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait. The L300 Go System may also: ● Facilitate muscle re-education ● Prevent/retard disuse atrophy ● Maintain or increase joint range of motion ● Increase local blood flow
Number of Output Modes	Biphasic Symmetric Mode only	2 modes: Biphasic Asymmetric and Symmetric
Number of Programs	• Gait • Tuning • Standby	● Gait ● Training/Exercise ● Clinician mode
Regulated Current or Regulated Voltage	Current	Current
Power Source	Rechargeable, Li-Ion, Prismatic, 3.7 V, 700 mAh	Control Unit: Li Coin Cell, CR2032, 3 V, 240 mAh EPG: Rechargeable, Li-Ion, Prismatic, 3.7 V, 1000 mAh Foot Sensor: Li Coin Cell, CR2032, 3 V, 240 mAh
Microprocessor-Controlled	Yes	Yes

Max Output Current (± 10%)	Thigh Channel: 102.4 mA @ 500 Ohm load	Lower Leg Channel: 102.4 mA @ 500 Ohm load	Thigh FSC: 100 mA @ 500 Ohm load	L300 Lower Leg FSC: 100 mA @ 500 Ohm load
Max Average Current Density [mARMS/cm²] [Over smallest electrode]	Thigh Channel: rectangular electrodes 0.26 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 50 cm^2)	Lower Leg Channel: Square electrodes 0.56 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 25 cm^2) round electrodes 1.37 mA_{rms}/cm^2 (Area 10.2 cm^2)	Thigh EPG: 0.18 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 74cm^2)	Lower Leg EPG: small cuff, gel electrodes 1.27 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 10.2cm^2)
Max Average Power Density, (mW/cm²)	Thigh Channel: rectangular electrodes A = 10.1x5.0 cm = 50 cm^2 1.7 mW/cm^2 @ 500 Ω	Lower Leg Channel: square electrodes A = 5x5 cm = 25 cm^2 3.4 mW/cm^2 @ 500 Ω round electrodes A =10.2cm^2 8.3 mW/cm^2 @ 500 Ω	Thigh EPG: 1.1 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 74 cm^2)	Lower Leg EPG: small cuff, gel electrodes 8.3 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 10.2 cm^2) regular cuff, gel electrodes 5.3 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 15.9 cm^2)
Stimulation Channels	2 channels		Thigh EPG: 1	Lower Leg EPG: 2 (functioning as a single channel with separately-adjustable medial / lateral stimulation intensity)
Electrodes used in the system	Hydrogel Electrodes: Square Electrodes: Male Snap connector; Surface area 25.0 cm2 Rectangular Electrodes: Male Snap connector; Surface area 50.0 cm2 Round Electrode: Male Snap connector; Surface area: 10.2cm2		Lower Leg FSC: ● 2 Hydro-Gel electrodes assembled on electrode bases, or ● 2 non-woven cloth electrodes assembled on electrode bases, or ● 2 non-woven cloth electrodes attached with snaps (also called “QuickFit” electrodes), or ● 3 non-woven cloth electrodes attached with snaps (segmented electrodes [also called “steering” electrodes], using common anode to allow separate adjustment of medial and lateral stimulation) Thigh FSC: ● 2 single, non-woven cloth electrodes attached with snaps	

Clinician Control/ Programming	Clinician uses the EvoWalk 1.0 companion application to set stimulation energy and temporal parameters related to the functional stimulation performance for dorsiflexion control and/or knee weakness control	Clinician uses the Clinician Programmer (CAPP) to set stimulation energy and temporal parameters related to the functional stimulation performance for dorsiflexion control and/or knee weakness control
Clinician Programmer (CAPP) Platform	Mobile Application (iOS and Android)	Tablet PC
User Control	Wearable unit: Users can press the button to power on, power off, enter pairing mode and toggle between standby mode (pause all stimulation) and active mode. Mobile application: From the app the user can set stimulation parameters, review usage data, toggle between standby mode (pause all stimulation), active mode, and tune the stimulation intensity before and during ambulation.	Using hand-held Control Unit, the mobile application (MAPP), or the EPG-based interface, the user can: • Turn system On/Off (via EPG only) and Start/Stop stimulation • Select Gait/Training program • Fine-tune stimulation intensity around working point set by the clinician • Test L300 Lower Leg EPG & Thigh EPG
Stimulation trigger source (when used for gait)	In gait mode, stimulation is triggered by the inertial measurement unit motion sensor embedded in the stimulator printed circuit board	In gait mode, stimulation is triggered by: (1) the motion sensor embedded in the EPG; or (2) Foot Sensor that detects Heel On & Heel Contact events during gait and transmits them wirelessly to the lower and thigh EPGs.
Communication method	EvoWalk 1.0 system - mobile user interface application: wireless Bluetooth (Low Energy) communication protocol	Control Unit – Lower Leg /Thigh EPG: wireless Bluetooth (Low Energy) communication protocol Gait Sensor – Lower Leg/Thigh EPG: wireless Bluetooth (Low Energy) communication protocol Clinician Programmer – EPG: wireless Bluetooth (Low Energy) communication protocol MAPP – Lower Leg /Thigh EPG: wireless Bluetooth (Low Energy) communication protocol
Maximum Phase Charge, (µC) @500 Ω	Lower leg: 200µs * 102mA = 20µC Thigh: 200µs * 102mA = 20µC	Not Reported

The indication for use is the same for EvoWalk 1.0 System and Bioness L300 Go System except EvoWalk 1.0 system is for adults only and Bioness L300 Go System is for pediatrics and adults. Additionally, EvoWalk 1.0 System is not indicated for muscle re-education, prevent/retard disuse atrophy, maintain or increase joint range of motion, or increase local blood flow. Both devices are worn on the user's leg, use hydrogel electrodes, have two channels of stimulation, use an embedded sensor to control stimulation, and both devices have a user interface through a mobile application. The EvoWalk 1.0 system eliminates some optional features of the Bioness L300 Go System including the separate thigh cuff, heel sensor, semi-rigid cuff, cloth electrode option, and dedicated remote control. Both systems control the stimulation in the gait program by reading the embedded motion sensor and applying algorithms and user-specified parameters such that the stimulation activates at a specific time within each gait cycle.

Summary of Nonclinical Tests Submitted

The EvoWalk 1.0 system has been verified and validated successfully for its intended use through a combination of original bench testing and verification and validation of all software and firmware. Based on the result of the nonclinical testing, Evolution Devices, Inc. concludes that the device is substantially equivalent to the predicate Bioness L300 Go System. The tests listed have been conducted to demonstrate that the EvoWalk 1.0 system performs as intended and is substantially equivalent to the predicate device.

- Technological Characteristics of Powered Muscle Stimulation - Stimulation Output Waveforms
- Motion analysis to validate the gait event detection algorithm
- Electrical Safety according to IEC 60601-1; IEC 60601-1-11
- Muscle and Nerve Stimulators according to IEC 60601-2-10
- Electromagnetic compatibility according to IEC 60601-1-2
- Software validation according to IEC 62304

Conclusion:

Evolution Devices believes the EvoWalk 1.0 system is substantially equivalent to the Bioness L300 GO system (**K173682**), and does not raise any new issues or concerns of safety or effectiveness. The evidence presented in the bench testing and non-clinical testing is sufficient to support the safety and effectiveness of the device.

The testing ensures that the device is safe for the intended use and will not cause harm to the user or interfere with other medical equipment or electronic devices. The software verification and validation testing ensure that the software used in the device operates as intended and is free of defects or errors.

In conclusion, the non-clinical evidence and testing considered for the bench testing 510k FDA submission for the EvoWalk 1.0 system supports the safety and effectiveness of the device.