DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 14, 2017

FlowAid Medical Technologies, Corp.
Mr. Jacob Brezel
CEO
44 Wall Street
New York, New York 10005

Re: K162987
Trade/Device Name: FA100 SCCD (Sequential Continuous Contraction Device)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: January 4, 2017
Received: January 5, 2017

Dear Mr. Brezel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162987

Device Name
FA100 SCCD (Sequential Continuous Contraction Device)

Indications for Use *(Describe)*

- Increasing local blood circulation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Preventing or retarding disuse atrophy
- Edema reduction

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

K162987

Traditional 510(k) Summary, as required by 21 CFR 807.92

A. Submitter: FlowAid Medical Technologies Corp.
44 Wall Street, 2nd Floor,
New York, NY 10005

Contact person: Mr. Jacob Brezel, CEO
Phone: (214) 461-3225
Email: Jacob@FlowAid.com

B. Date Prepared: February 13, 2017

C. Device Name and Classification:

Trade name:	FA100 SCCD (Sequential Continuous Contraction Device)
Common name:	Neuromuscular Electrical Stimulator (NMES)
Classification name:	Powered Muscle Stimulator
Regulatory Class:	Class II
Product Code:	IPF
Review Panel	Physical Medicine

D. Predicate Device: IF 3Wave - K050046

E. Device Description:

The FA100 SCCD is a portable, battery powered, hand-held 4-channel electrical stimulator (single unit) intended to provide continuous, sequential stimulation of the calf muscles. The FA100 SCCD designed to be user friendly and simple to use, with a large liquid crystal display (LCD) screen that displays the treatment mode currently in use and the selected intensity level for the patient to select a comfortable therapy session as recommended by the patient's healthcare provider.

The FA100 SCCD system provides three preset treatment programs, which enable the patient to choose among three pulse frequencies:

1. 4 Hz (program AA)
2. 9 Hz (program VE – the default setting of the device)
3. 14 Hz (program PA)

Pulse frequency is the only difference between the three programs and is selected for patient comfort during the treatment as recommended by the patient's healthcare provider. The stimulation provided by the FA100 SCCD rotates in a continuous, sequential pattern through the four channels. The rotation through the channels is directly related to the frequency setting, i.e., slowest for the 4 Hz program and fastest for the 14 Hz program. All programs effectively contract the muscles and increase blood flow. The only other parameter that can be varied is the stimulus intensity, which is set

by the user to achieve the maximum tolerable contraction. Otherwise, the pulse shape (rectangular, symmetrical, bi-phasic), pulse width (500 µsec), and stimulation pattern (sequential channel activation) are the same for all three programs.

F. Indication for Use/Intended Use:

The FA100 SCCD is indicated for use in:

- Increasing local blood circulation,
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
- Preventing or retarding disuse atrophy
- Edema reduction

G. Substantial Equivalence

The table below provides the basic unit characteristics and output specifications for the subject and predicate device as outlined in the Powered Muscle Stimulator Guidance Document issued on June 9, 1999.

	New Device	Predicate Device	Basis for Substantial Equivalence
510(k) Number	K162987	K050046	N/A
Device Name & Model	FA100 SCCD	IF 3Wave	NA
Manufacturer	FlowAid	Empi	N/A
Indications for Use	<u>As a muscle stimulator</u> • Increase local blood circulation • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Prevention or retardation of disuse atrophy • Reduction of edema	<u>As a muscle stimulator</u> • Increase local blood circulation • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Relax muscle spasms • Prevent or retard disuse atrophy • Maintain or increase range of motion • Muscle re-education <u>As a Pulsed DC Stimulator</u> • Reduction of edema (under the negative electrode) • Reduction of muscle spasm	Indications for new device are a subset of those for predicate device.* Clinical data is provided to support indications for use.

	New Device	Predicate Device	Basis for Substantial Equivalence
		• Influencing local blood circulation (under the negative electrode) • Retardation or prevention of disuse atrophy • Facilitation of voluntary motor function • Maintenance or increase of range of motion <u>As an interferential stimulator</u> • Relieve acute pain • Relieve and manage chronic pain • Relax muscle spasms • Maintain and increase the range of motion • Increase local blood circulation	
Basic Unit Characteristics			
Power Source	Four 1.2VDC GP NiMH battery cells	Rechargeable lithium-ion polymer battery	Both devices are battery powered.
Method of Isolating User from Mains	Plastic slider over the charging port prevents charging when electrode cable is connected to the device	Not stated in 510(k) Summary	New device cannot be used for treatment when the battery is connected to mains for charging.
Number of Output Modes	1 NMES	3 NMES Pulsed stimulation Interferential stimulation	New device is a subset of predicate device.*
Number of Output Channels - Synchronous or alternating? - Method of channel isolation?	4 Sequential Stimulation of electrode pairs: 4-1, 1 - 2, 2 - 3, 3 - 4 Capacitor	2 Unknown Transformer	New device has 4 output channels, but only 2 are active at a time.* Both are accepted methods of channel isolation.

	New Device	Predicate Device	Basis for Substantial Equivalence
Regulated current or voltage	Current regulated	Current regulated	Same
Microprocessor controlled?	Yes	Yes	Same
Automatic overload trip	Yes	No	Automatic overload trip of new device is added safety feature.
Automatic no-load trip	Yes	Yes	Same
Automatic shut-off	Yes – at end of battery life, approximately 50 hours of continuous treatment	Yes	Same
Patient over-ride control	Yes	Yes	Same
Indicator Display: - On/off status - Low battery - Voltage/ current level	 Yes Yes Yes – numerical indication of signal intensity (voltage value)	 Yes Yes Yes	Same
Number of Preset Programs	3	3 for NMES	Same for NMES
Timer range in minutes	No timer Device will operate until turned off by user or battery depleted.	10 – 60 min in 5 min increments	Timer not needed for safe application.
Compliance with voluntary standards	Yes	Yes	Same
Compliance with 21 CFR 898	Yes	Not stated in 510(k) Summary	Compliant with electrode performance standard.
Weight	230 g, including batteries	340 g, including battery	Both are lightweight and portable.
Dimensions	2.8” x 5.1” x 1.1”	3.9” x 6.3” x 1.4”	Both are small.
Housing Materials of Construction	Injection molded plastic	Injection molded plastic	Same

	New Device	Predicate Device	Basis for Substantial Equivalence
Output Specifications			
Waveform	Symmetrical bi-phasic rectangular wave with 0 net DC	NMES - Symmetrical bi-phasic square wave with 0 net DC	Essentially the same.
Maximum output voltage (500 Ω load)	80 V (±10%)	Not stated in 510(k) Summary	80V is within the acceptable range of max voltage for NMES devices.*
Maximum output current (500 Ω load)	160 mA (±10%)	100 mA	160 mA is within the acceptable range of max current for NMES devices.*
Pulse Width	Fixed – 500 µsec	70 – 300 µsec	500 µsec is within the acceptable range of pulse widths for NMES devices.*
Frequency	4 Hz, 9 Hz, or 14 Hz depending on therapy setting	10 – 80 Hz	4, 9 and 14 Hz are within the acceptable range of frequencies for NMES devices.*
Net charge – how achieved	0 µC, phase balancing	0 µC, phase balancing	Same
Maximum phase charge	8 µC	30 µC for NMES 60 µC for Pulsed	8 µC is within the acceptable range of phase charge for NMES devices*
Maximum Current Density	6.4 mA/cm^2	0.19 mA/cm^2 for NMES (average) 0.13 mA/cm^2 for Pulsed (average)	6.4 mA/cm^2 is within the acceptable range of current densities for NMES devices.*
Maximum Power Density	0.000041 W/cm^2	0.019 W/cm^2 for NMES (average) 0.013 W/cm^2 for Pulsed (average)	0.000041 W/cm^2 is within the acceptable range of power densities for NMES devices.*
Burst mode	*N/A*	*N/A*	Same
ON Time (sec) **OFF Time (sec)**	Sequential channel activation. Channel ON and OFF times depend on program (frequency).	ON: 1 – 30 s OFF: 1 – 60 s	Sequential continuous contraction pattern of new device is substantially equivalent to

	New Device	Predicate Device	Basis for Substantial Equivalence
	Program AA (4 Hz) ON: 1 s, OFF: 3 s Program VE (9 Hz): ON: 0.44 s; OFF: 1.32 s Program PA (14 Hz): ON: 0.29 s; OFF: 0.87 s One channel always ON for continuous stimulation.		predicate and other NMES devices that offer varying ON / OFF patterns for electrode stimulation.*
Electrodes	Manufactured by Top Rank, China and cleared under K132588. Hydrogel applied to silver electrode. Biocompatibility has been established. Single patient use, can be reused many times before disposal, recommend replacing every 10 days.	Electrode pads not described in 510(k) Summary	FA100 SCCD electrodes were previously cleared by FDA.

*See Discuss of Differences below.

Discussion of Differences

FDA has cleared more than 500 powered muscle stimulators under Product Code IPF, encompassing a wide variety of technical specifications, all of which have been found safe and effective for neuromuscular electrical stimulation. Where appropriate, other legally marketed NMES devices are cited below to demonstrate that the technological differences of the FA100 SCCD as compared to the named predicate device do not raise new questions of safety or effectiveness that have not previously been considered by FDA for NMES devices. In addition, clinical data from studies of the FA100 SCCD are summarized in Section I of this 510(k) Summary to support the safety and effectiveness of the new device for its indications for use.

1. Indications for Use: The FA100 SCCD indications for use are a subset of the predicate indications for use. The proposed indications for the FA100 SCCD are all supported by clinical studies conducted using the device (see Section I). The FA100 SCCD does not have any indications for use that are not also cleared for the predicate device; therefore, no new questions of safety or effectiveness are raised by this difference.
2. Number of output channels: The FA100SCCD has four output channels as compared to two for the predicate device. However, this does not raise any new questions of safety or effectiveness because only one channels is active at any one time to drive one electrode pair. In addition, FDA has cleared many other NMES devices that have

more than two output channels (e.g., RS-4i Plus Sequential Stimulator, K112348, providing options of 2, 4, or 8 electrodes applied to multiple anatomical sites).

3. Maximum output current (stimulus intensity): The stimulus intensity of the FA100 SCCD is set to achieve visible contraction of the calf muscles at a level tolerable to the patient. Stimulus intensity can be varied from 1V to 80V in 1V increments. The maximum voltage corresponds to a maximum current of 160 mA, which is somewhat higher than that of the predicate device (100 mA max), but is within the specifications for other legally marketed NMES devices (e.g., Sys*Stim 208/208A, K031017, with a maximum output voltage of 92 V and a maximum output current of 184 mA).
4. Pulse width: The FA100 SCCD has a fixed pulse width of 500 µsec, which is somewhat longer than that of the predicate device (300 µsec max), but is within the specifications for other legally marketed NMES devices (e.g., geko T-1, K133638, 560 µsec max pulse width).
5. Frequency: The FA100 SCCD offers three stimulus settings that differ only in the pulse frequency: 4 Hz, 9 Hz and 14 Hz. While the two lowest frequencies are somewhat lower than the range offered by the predicate device (10 – 80 Hz), they are within the range offered by other legally marketed NMES devices (e.g., geko T-1, K133638, 1 Hz fixed pulse frequency). Clinical data are provided to demonstrate that the low frequency settings of the FA100 SCCD are safe and effective for the device intended uses.
6. Maximum phase charge: The 8 µC max phase charge for the FA100 SCCD is lower than that of the predicate device (30 µC max for NMES), which indicates added safety for the new device. Clinical data are provided to demonstrate that the FA100 SCCD is effective for its intended uses.
7. Maximum current density: The 6.4 mA/cm^2 max current density for the FA100 SCCD is higher than the current density stated in the 510(k) summary for the predicate device (0.19 mA/cm^2 for NMES); however, this is stated as an average, not maximum, current density. The max current density for the FA100 SCCD is the same as that for the geko T-1 (6.67 mA/cm^2, see K133638).
8. Maximum power density: The 0.000041 W/cm^2 max power density for the FA100 SCCD is lower than for the predicate device (0.019 W/cm^2 for NMES, stated as average), but is the same as that of the geko T-1 (0.000044 W/cm^2, see K133638).
9. Stimulation sequence (On/Off times): The FA100 SCCD provides a continuous sequential stimulation pattern in which one of the four channels are on at a time. The On and Off times for each channel are driven by the chosen frequency. The predicate device and many other powered muscle stimulators provide flexibility to enable varying On and Off times for each channel.

H. Non-Clinical Performance Data

To demonstrate safety and effectiveness of the FA100 SCCD and to comply with the requirements of the FDA Guidance Document "Guidance Document for Powered Muscle Stimulator 510k's) and to demonstrate substantial equivalence to the predicate device, FlowAid has completed a number of non-clinical performance tests. The FA100 SCCD

meets established requirements for overall design, electrical safety and software validation confirming that the design outputs meet design input requirements and established specifications.

The FA100 SCCD device successfully passed all testing in accordance with internal requirements, national and international standards and the FDA Guidance Document cited above. These included:

- Electrical safety per IEC 60601-1:2012
- EMC testing per IEC 60601-1-2: 2007
- Electrical testing per IEC 60601-2-10:2012 (Particular requirements for the safety of nerve and muscle stimulators)
- Electrical testing per IEC 60601-1-11:2010 (Basic safety, equipment used in home health environment
- Software validation per IEC 62304:2006

The FA100 SCCD passed all the testing in accordance with internal requirements, national standards, and international standards. Internal verification and validation testing confirms that all product specifications and user requirements have been met, which support the intended use and technological characteristic of the device when compared to the predicate device. The information presented supports that the FA100 SCCD is substantially equivalent to the referenced predicate device.

I. Clinical Performance Data:

Publication	Summary
Gimmelreich D, Karsilnikov V, Litman L, Rosenblum J. Sequential contraction compression devices reduce leg circumference in patients with chronic venous insufficiency. *J Vasc Med & Surg* 2016; 4(4):283. doi 10.4172/2329-6925.1000283.	Compared the use of the FA100 SCCD to compression therapy for the treatment of edema in 15 patients with chronic venous insufficiency (CVI) in both legs. The FA100 SCCD was used in the home on the same leg for 2 hours daily for 30 days. The compression device was used for the same length of time on the other leg. After 30 days of treatment, the average circumference at both the ankle and calf decreased for the legs treated with the FA100 SCCD (21.9% and 19.5%, respectively, both p<.001). In addition, the average changes in ankle and calf circumference were greater for the FA100 SCCD treated legs as compared to the legs treated with compression. No adverse events were reports.

J. Statement of Substantial Equivalence:

FlowAid has demonstrated that the FA100 SCCD (Sequential Continuous Contraction Device) is substantially equivalent to the predicate device because it has the same intended use as a powered muscle stimulator, is intended to be used for a subset of the indications for use, and has similar technological characteristics. Clinical data are provided to demonstrate that the FA100 SCCD is safe and effective for the proposed indications for use.