
510(K) SUMMARY

GENERAL

SUBMITTOR:

NeuroMotion Inc.

401 11044 - 82 Avenue NW
Edmonton, Alberta
Canada T6G 0T2

Phone (403) 433-1700
Fax (403) 433-2893

Contact: Brian Zerb, Director of Quality

DATE PREPARED:

98-01-27

DEVICE:

Proprietary Name - WalkAide
Common/Usual Name - External Functional Neuromuscular Stimulator
Classification Name - External Functional Neuromuscular Stimulator
Classification Code - Class II

PREDICATE DEVICES:

Medtronic, Inc.	Respond III	K920436
Medtronic, Inc.	Respond Select®	K903434C
Empi, Inc.	Model 2000	K800380A
Verite	Model 817 VERI/DFS™	K813515

DEVICE DESCRIPTION:

The WalkAide is an external functional electrical stimulator. It is a small device that attaches to the leg just below the knee, near the head of the fibula. During a gait cycle, the WalkAide stimulates the common peroneal nerve, which innervates the tibialis anterior and other muscles that cause dorsiflexion of the ankle.

Users of the WalkAide are people who have lost the ability to voluntarily lift their foot by flexing the ankle, often as a result of damage to the central nervous system such as stroke, spinal cord injury, and traumatic brain injury. This stimulation will not work with people who have damage to the lower motor neurons/peripheral nerves.

INTENDED USE:

The NeuroMotion WalkAide is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of gait, the WalkAide electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.

COMPARISON TABLE

Feature	WalkAide	Marketed Devices		
Device Name	WalkAide	Respond III and Respond Select®	EMPI Model 2000	Verite Model 817 VERI/DFS
Constant Current Range (1000 Ohm load)	0 - 95mA	0 - 100mA		0 - 50 mA
Pulse Duration (µsec.)	200	300	+ ve: 500	110
Frequency Range (PPS)	25	1 - 80	20 - 50	50
Electrode Size and Shape	2.5cm diameter Round	Various, including SnapEase® 2.5cm diameter	3cm & 5cm diameter Round	4.3cm diameter Round

DISCUSSION OF SUBSTANTIAL EQUIVALENCE:

STIMULATION CHARACTERISTICS

Pulse shape, pulse width, pulse intensity, and pulse repetition frequency are substantially equivalent to the predicate devices.

STIMULATION ACTIVATION TRIGGER MECHANISM

Beside being capable of using a foot sensor to trigger stimulation, the WalkAide mainly utilizes a built-in tilt sensor to trigger stimulation on and off points in an equivalent manner to a foot sensor.

ELECTRODES

The WalkAide electrodes are similar to certain electrodes listed with the predicate devices. They are 2.5cm in diameter, contain an integral snap connector, and are pre-gelled.

TESTING:

The following tests were conducted to aid in the determination of substantial equivalence, and successfully completed:

- Stimulation Pulse Characteristics
- Electrode Current Density Spread
- Foot Sensor Characteristics
- Stimulation Trigger Source Timing
 - Foot Sensor
 - Tilt Sensor
- Clinician System Application Program

CONCLUSION:

Based on the information provided above, NeuroMotion believes that the WalkAide is substantially equivalent to the existing legally marketed devices, and does not alter or introduce any issues regarding safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 1998

Mr. Brian Zerb
Director of Quality
NeuroMotion, Inc.
401 11044-82 Avenue
Edmonton, Alberta
Canada T6G 0T2

Re: K974514
WalkAide
Regulatory Class: II
Product Codes: GZI and IPF
Dated: November 27, 1997
Received: December 1, 1997

Dear Mr. Zerb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

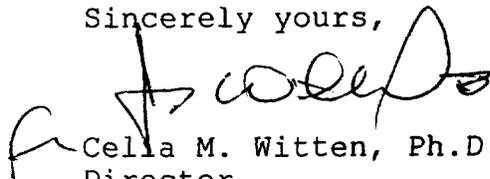
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Cella M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K974514

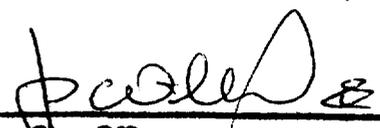
Device Name: WalkAide

Indications for Use:

The NeuroMotion WalkAide is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of gait, the WalkAide electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974514

Prescription Use
(Per 21 CFR 801.109)

OR

Over the Counter