SEP 2 1 2005 K052329

510(k) Summary
for the
Innovative Neurotronics, Inc.
WalkAide System

1. SPONSOR

Innovative Neurotronics, Inc.
Two Bethesda Metro Center, Suite 1200
Bethesda, Maryland

Contact Person: Fayyaz Memon – Director of Quality and Manufacturing
Telephone: 1-888-884-6462 ext. 1005

Date Prepared: August 25, 2005

2. DEVICE NAME

Proprietary Name:	WalkAide
Common/Usual Name:	External Neuromuscular Functional Stimulator
Classification Names:	External Neuromuscular Functional Stimulator
Classification Number:	21 CFR 882.5810
Product Code:	GZI

3. PREDICATE DEVICES

Neuromotion WalkAide System– K974514

4. INTENDED USE

The Innovative Neurotronics WalkAide System 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.

5. 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. The WalkAide System consists of the WalkAide Patient Kit and the WalkAide Clinician Kit . The WalkAide Patient Kit comprises of all the components and accessories that the patient will take home and use. The Clinician System comprises the accessories that a clinician (i.e., orthotic specialist, physiotherapist, occupational therapist, etc.) will use to set up a patient's WalkAide.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The intended use and technological characteristics such as pulse shape, pulse width, pulse intensity, stimulation trigger mechanism, and other characteristics of the proposed WalkAide are either identical or substantially equivalent to the parent WalkAide devices.

Applicable performance and safety testing was performed to verify technological and functional characteristics including any design modification. Any design modifications do not raise any safety or effectiveness issues.

7. CONCLUSIONS

Based on the information provided in this premarket notification, Innovative Neurotronics believes that the proposed WalkAide is substantially equivalent to the parent Walk-Aide.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Mr. Fayyaz Memon
Director of Quality and Manufacturing
Innovative Neurotronics, Inc.
Two Bethesda Metro Center, Suite 1200
Bethesda, Maryland 20814

Re: K052329
Trade/Device Name: Walk Aide External Dunctional Neuromuscular Stimulator
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: II
Product Code: GZI
Dated: August 25, 2005
Received: August 25, 2005

Dear Mr. Memon:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K052329

Device Name: Innovative Neurotronics, Inc., WalkAide External Functional Neuromuscular Stimulator

Indications for Use:

The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (WalkAide System) 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 System 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.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052329