510(k) Summary
For The
ODFS Dropped Foot Stimulator

1. SPONSOR

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2. Device Name

Trade/Proprietary Name: The ODFS Dropped Foot Stimulator
Common/Usual Name: External Functional Neuromuscular Stimulator (FES)
Classification Name: External Functional Neuromuscular Stimulator (FES) Powered Muscle Stimulator (NMES)
Classification Code: Class II
Product Codes: GZL and IPF
3. **Predicate Devices**

<table>
<thead>
<tr>
<th>Predicate Name</th>
<th>Company</th>
<th>K Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMPI Focus Model 795</td>
<td>EMPI</td>
<td>K951951</td>
</tr>
<tr>
<td>WalkAide</td>
<td>NeuroMotion</td>
<td>K974514</td>
</tr>
</tbody>
</table>

4. **Device Description**

The ODFS Dropped Foot Stimulator (ODFSIII Version 6.2) is an external functional neuromuscular stimulator. The ODFS Dropped Foot Stimulator electrically stimulates the common peroneal nerve which may produce contraction of the appropriate muscles that cause dorsiflexion of the ankle in individuals who have lost the ability to do so following neurological injury.

The device is comprised of a small belt-worn, single-channel, foot-switch controlled stimulator used with skin-surface stimulating electrodes. The surface electrodes are typically placed over the common peroneal nerve as it passes near the head of the fibula and the motor point of the tibialis anterior in the lower leg. The heel switch allows the delivery of stimulation to be triggered according to the gait of the user.

5. **Intended Use**

The ODFS Dropped Foot Stimulator is intended to provide ankle dorsiflexion in individuals with dropped foot following an upper motor neuron injury. During the swing phase of gait, the ODFS electrically stimulates muscles in the leg and ankle of partially paralyzed individuals to provide flexion of the foot and may thus improve the individual’s gait. Additional benefits of Functional Electrical Stimulation (FES) may include muscle re-education, prevention/retardation of disuse atrophy, maintained or increased joint range of motion, and increased local blood flow.
6. **Technological Characteristics and Substantial Equivalence**

<table>
<thead>
<tr>
<th>Feature</th>
<th>ODFS Stimulator</th>
<th>SMPL Foot Model 798</th>
<th>WalkAide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waveform</td>
<td>Biphasic</td>
<td>Biphasic</td>
<td>Not available</td>
</tr>
<tr>
<td></td>
<td>(Symmetrical and Balanced Asymmetrical)</td>
<td>(Symmetrical and Balanced Asymmetrical)</td>
<td></td>
</tr>
<tr>
<td>Pulse Width</td>
<td>7 (+4) to 365 (+20) μsec (patient selectable)</td>
<td>300 μsec</td>
<td>200 μsec</td>
</tr>
<tr>
<td>Frequency (Hz)</td>
<td>40 (+4) Hz</td>
<td>25, 30, 35, 45, 50, 80 Hz</td>
<td>25 Hz</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>To provide ankle dorsiflexion in individuals with dropped foot following an upper motor neuron injury. During the swing phase of gait, the ODFS electrically stimulates muscles in the leg and ankle of partially paralyzed individuals to provide flexion of the foot and may thus improve the individual's gait. Additional benefits of Functional Electrical Stimulation (FES) may include muscle re-education, prevention/retardation of disuse atrophy, maintained or increased joint range of motion, and increased local blood flow.</td>
<td>As a TENS device: Symptomatic relief and management of chronic intractable pain; adjunctive treatment for postsurgical and post-trauma acute pain. As a NMS/NMES device: Relaxation of muscle spasm; prevention or retardation of disuse atrophy; increasing local blood circulation; muscle re-education; immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis; maintaining or increasing range of motion. As a FES device: Stimulating muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient’s gait.</td>
<td>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 FES may include prevention/retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.</td>
</tr>
<tr>
<td>Accessories</td>
<td>Heel switch</td>
<td>Heel switch, Hand switch</td>
<td>Heel switch, Tilt sensor</td>
</tr>
<tr>
<td>Electrode Size and Shape</td>
<td>5.0 cm x 5.0 cm square = 25 cm²</td>
<td>5.1 cm²</td>
<td>2.5 cm round</td>
</tr>
</tbody>
</table>

7. **Performance Testing**

The ODFS system has been subjected to testing to verify that the device meets its key output specifications. All units tested met product specifications.

Testing included:

- Functional verification testing of output and operational characteristics
- IEC 60601-2-10 (as applicable).
- ISO 60601-1-2 (as applicable).

Based on the information provided, the ODFS Dropped Foot System is substantially equivalent to legally marketed predicate devices.
Re: K050991
Trade/Device Name: ODFS Dropped Foot Stimulator
Regulation Number: 21 CF 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: II
Product Code: GZI
Dated: July 8, 2005
Received: July 11, 2005

Dear Ms. Lechman:

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/dsma/dsmain.html

Sincerely yours,

Miriam C. Provost, Ph.D
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 (if known): K050991

Device Name: ODFS Dropped Foot Stimulator

Indications for Use:

The ODFS Dropped Foot Stimulator is intended to provide ankle dorsiflexion in individuals with dropped foot following an upper motor neuron injury. During the swing phase of gait, the ODFS electrically stimulates muscles in the leg and ankle of partially paralyzed individuals to provide flexion of the foot and may thus improve the individual's gait. Additional benefits of Functional Electrical Stimulation (FES) may include muscle re-education, prevention/retardation of disuse atrophy, maintained or increased joint range of motion, and increased local blood flow.

The ODFS is a medical device and should only be used under medical supervision for adjunctive therapy for the treatment of dropped foot following an upper motor neuron injury.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 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 Number: K050991