K102115

LEADING REHABILITATION
THROUGH TECHNOLOGY

Odstock Medical Limited

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MAR 3 0 2011

510(k) Summary
For the

ODFS® Pace

[Section 5 of the Submission]

5.1 Sponsor/Owner

Odstock Medical Limited
Laing Building
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ
United Kingdom

Odstock Medical Ltd is a Registered Establishment, number: 3005344585

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Date prepared	21 July 2010, with revisions 11&14 March 2011

US Agent

Boston Brace International 20 Ledin Drive Avon, MA 02322 USA	Phone: 800-262-2235 Fax: 800-634-5048

5.2 DEVICE NAME

Trade/Proprietary Name:	ODFS®-Pace
Common/Usual Name:	External Functional Neuromuscular Stimulator (FES)
Classification Name:	External Functional Neuromuscular Stimulator (FES) Powered Muscle Stimulator (NMES)
Classification No.	21 CFR 882.5810
Classification Code:	Class II
Product Codes:	GZI and IPF

5.3 Predicate Devices

Predicate Device	K number	Comment
EMPI Focus Model 795	K951951	EMPI
ODFS III V6.2	K050991	Odstock Medical Ltd (transferred from Salisbury District Hospital)

5.4. Device Description

The ODFS® Pace is an external functional neuromuscular stimulator. It consists of a small, body worn, single channel stimulator which is triggered by a wired footswitch worn in the shoe. Electrical pulses are generated by the device in order to stimulate muscles in the lower limb. Triggering with a footswitch permits the stimulation to be varied according to the gait of the user. Stimulation produces contraction of the appropriate muscles to cause dorsiflexion of the ankle in individuals who have impaired or absent ability to pick up their foot during walking as a result of a neurological injury. This partial paralysis affecting the foot is commonly known as 'drop foot' or 'dropped foot'.

The electrical stimulation is delivered via self adhesive skin surface electrodes. The electrodes may be flexibly placed according to the optimum response of the patient but typically are located over the common peroneal nerve as it passes near the head of the fibula.

For individuals presenting with weakness and/or spasticity a muscle stimulation exercise program can be delivered by the ODFS® Pace. In this case the footswitch trigger is not used and the ODFS® Pace functions as a powered muscle stimulator. A clinician would determine the need for this application which can enabled from a setup option in the ODFS® Pace. (Default is to have the exercise disabled)

5.5 Intended Use

The ODFS® Pace is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. By detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function. There may be additional benefits from FES such as muscle re-education,

prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local blood flow.

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

5.6 Technological Characteristics and Substantial Equivalence

The technological characteristics of the ODFS® Pace and predicate devices are tabulated below. All the devices are battery powered and deliver electrical stimulation pulses of similar waveform, pulsewidth and frequency. The ODFS® Pace is a development of the ODFS III v6.2 and therefore has identical indications for use as an FES device. These indications correspond to the FES functions of the EMPI device. The exercise function of the ODFS® Pace corresponds to and is substantially equivalent to the NMS/NMES indications of the EMPI device.

5.6 Technological Characteristics and Substantial Equivalence - Table

Feature	ODFS® Pace	ODFS III v6.2	EMPI Focus 795
Waveform	Biphasic (symmetrical and balanced asymmetrical)	Biphasic (symmetrical and balanced asymmetrical)	Biphasic (symmetrical and balanced asymmetrical)
Pulsewidth	0μs - 360μs (±10%) according to patient selection (3.6 μs steps)	7μs - 365μ (±10%) according to patient selection	300μs
Frequency	Default is 40Hz. 20 – 60 Hz in 5Hz steps available	40Hz ± 10%	25, 30, 35, 45,50,80Hz
Indications for use	The ODFS® Pace is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. By detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function. There may be additional benefits from FES such as muscle re-education, prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local	To provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. By detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function. There may be additional benefits from FES such as muscle re-education, prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local blood flow.	TENS device Symptomatic relief and management of chronic intractable pain. Adjunctive treatment for post-surgical 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 reducation; 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

	blood flow. As a NMS/NMES device: relaxation of muscle spasm; prevention or retardation of disuse atrophy; increasing local blood circulation; muscle re-education; maintaining or increasing range of motion.		the leg and ankle of partially paralysed patients to provide flexion of the foot and thus improve the patients gait.
Accessories	Heel switch	Heel switch	Heel switch, hand switch
Electrode size & shape	5cm x 5cm	5cm x 5cm	5.1cm^2

5.7 Performance testing

The ODFS® Pace system has been subjected to testing to verify that the device meets its functional and output specifications. Production units pass functional testing of stimulator controls, settings and indicators, stimulus output and timing, footswitch operation, and power consumption.
Parameters measured under the conditions specified in *FDA Guidance Document for Powered Muscle Stimulator 510(k)s* are included in the ODFS® Pace 510(k) submission.

In addition to functional and operational performance testing the ODFS® Pace passed the applicable requirements of the following standards:

- ISO 60601-1-1:2006 Medical Electrical Equipment – General requirements for basic safety and essential performance.
- ISO 60601-1-2:2007 Medical Electrical Equipment – General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO 60601-2-10:2001 Medical electrical equipment. Particular requirements for the safety of nerve and muscle stimulators

Based on the information provided above the ODFS® Pace is substantially equivalent to legally marketed predicate devices.

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Version	Comment	Author
3->4	Amend indications for use and add regulation number for classification name.	S.Crook 14/3/11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Odstock Medical, Ltd.
c/o Dr. Steven Crook
Quality and Regulatory Manager
Salisbury District Hopital
Salisbury, Wilitshire
United Kingdom, SP2 8BJ

MAR 30 2011

Re: K102115
Trade/Device Name: ODFS® Pace
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: January 21, 2011
Received: January 26, 2011

Dear Dr. Crook:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K102115

Device Name: ODFS® Pace

Indications for use: The ODFS® Pace is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. By detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function. There may be additional benefits from FES such as muscle re-education, prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local blood flow.

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

Prescription use__X_ (Part CFR 801 Subpart D) and/or Over-The-Counter Use_____ (CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation, (ODE)

(Division Sign-Off)

Division of **Ophthalmic, Neurological and Ear,**

Nose and Throat **Devices**

510(k) Number K102115