

**510(k) Summary**

**Ortho D<sub>x</sub> Neuromuscular Stimulator**

**Model 6700S**

V971542

**Product:**

Ortho D<sub>x</sub> Neuromuscular Stimulator, Model 6700S

AUG 14 1997

**Classification:**

Class II

**Manufacture:**

Rehabicare Inc.

1811 Old Highway 8  
New Brighton, MN 55112  
Phone No. (612) 631-0590

**Contact:**

Gary L. Moore  
Phone No. (612) 638-0437

**Predicate Products:**

- GV II<sup>TM</sup> Neuromuscular Stimulator, Model 9700/7000S, K881082
- Neuromuscular II (NMIII<sup>TM</sup>), Model 6800S, K840346
- TRI-STIM Stimulator, Muscle, Electrical Powered, Registration No. not known

**Indications For Use:**

The Ortho D<sub>x</sub>, a non-invasive electrical stimulator that combines symmetrical biphasic neuromuscular stimulation with high volt pulsed direct current neuromuscular stimulation to be used under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. It is used to, relax muscle spasm, prevent or retard disuse atrophy, increase local blood circulation, reeducate muscles, prevent venous thrombosis with immediate post surgical stimulation in calf muscles, and increase range of motion.

**Device Description:**

The Ortho D<sub>x</sub> is a non-invasive electrical stimulator that combines symmetrical biphasic neuromuscular stimulation with high volt pulsed direct current neuromuscular stimulation that will operate in both modes simultaneously or independently. This system is a prescription device intended for use on patients who are undergoing rehabilitation for medical diseases and conditions on the order of a licensed practitioner.

**Summary of Testing:**

The output wave form, amplitude, pulse width, pulse rate, treatment time, NMS off time, NMS ramp up time and NMS ramp down time have been verified to the technical requirements listed in the operators manual. All measurements were taken at room temperature (72°C) with a relative humidity of 50% using a calibrated 5V power supply with a maximum capacity of 3 ampere continuous current and calibrated measurement equipment. These values are within and/or identical to the operating parameters of the predicate devices. The Ortho D<sub>x</sub> neuromuscular stimulator uses the same power supply and proposes no additional safety considerations than the legally marketed predicate devices (NM II/III and GV II). The Line Powered Repac™ employees a UL approved power supply and is legally marketed with the predicate devices (NM II/III and GV II).

**Substantial Equivalence Summary:**

The Ortho D<sub>x</sub>™ is a neuromuscular stimulator with a symmetric biphasic output wave form identical to the Mentor Neuromuscular II (NM III™), Model 6800S, Neuromuscular Stimulator, Registration Number, K840346, and a high volt pulsed current output wave form identical to the GV II™, Model 9700, High Voltage Pulsed Galvanic Stimulator, Registration Number, K881082. This type of unit, combining both types of output wave forms, is similar to a predicate device, the TRI-STIM™, Stimulator, Muscle, Electrical Powered, manufactured by Henley, a Division of Maxxim Medical, 104 Industrial Blvd., Sugarland, TX 77478 (registration number unknown).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Gary L. Moore  
Director of Engineering  
Rehabilitare Inc.  
1811 Old Highway 8  
New Brighton, Minnesota 55112

Re: K971542  
Ortho Dx™ Neuromuscular Stimulator  
Regulatory Class: II  
Product Code: IPF  
Dated: July 29, 1997  
Received: August 4, 1997

AUG 14 1997

Dear Mr. Moore:

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.

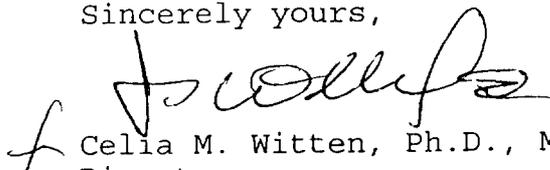
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

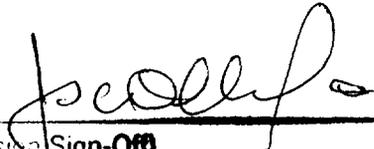


Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Statement for Indication of Use:**

The Ortho D<sub>x</sub>, a non-invasive electrical stimulator that combines symmetrical biphasic neuromuscular stimulation with high volt pulsed direct current neuromuscular stimulation to be used under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. It is used to, relax muscle spasm, prevent or retard disuse atrophy, increase local blood circulation, reeducate muscles, prevent venous thrombosis with immediate post surgical stimulation in calf muscles, and increase range of motion.

  
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(Authorized Sign-Off)  
\_\_\_\_\_  
of General Restorative Devices  
510(k) Number 12971542

Prescription Use X  
(Per 21 CFR 801.109)