K023230

MAY 0 5 2003

510(k) SUMMARY

This summary is provided in accordance with the Safe Medical Device Act of 1990 (SMDA). The information provided in the 510(k) Premarket Notification was in accordance with 21 CFR 807.87.

1. Applicant, Official Correspondence and Owner of 510(k)

   Applicant/Owner: Western Clinical Technology Systems, Inc.
   6737 Owen Hill Road
   College Grove, TN 37046
   (615) 368-2426

   Correspondent: W.T. Workman, MS, CHT
   18111 Copper Ridge Drive
   San Antonio, TX 78259
   (210) 490-6999

2. Trade Name: EchoPulse Muscle Stimulator System, Model 800

3. Common Name: Powered muscle stimulator (89IPF)

4. Classification: 21 CFR 890.5850 Powered Muscle Stimulator, Class II

5. Predicate Device: Bio-Stym 250, Microvas Technologies, Inc. (K891987)

6. Device Description: The EchoPulse 800 is an eight channel, synchronous, biphasic, powered muscle stimulator. It produces a maximum output voltage of 105 V at 500 ohm, a maximum output current of 210 mA at 500 ohm and has a pulse width of 180 usec. The 3 pin connector leads are each 72 inches long. The electrodes are 3 inch diameter Carbonflex electrodes and use 3 inch disposable sponge fabric wetable pads for application on the skin. The EchoPulse 800 measures 19 inches wide, 5 ¼ inches tall, and 12 ½ inches deep. It weighs 27 ¼ pounds and is rack mountable.

7. Indications for Use: Relaxation of muscle spasms

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 5 2003

Western Clinical Technology Systems, Inc.
c/o Mr. W.T. Workman
Workman Hyperbaric Services, Inc.
18111 Copper Ridge Drive
San Antonio, Texas 78259-3612

Re: K023230
Trade/Device Name: EchoPulse Muscle Stimulator System - Models 800, 400 and 100
Regulation Numbers: 21 CFR 890.5850
Regulation Names: Powered muscle stimulator
Regulatory Class: Class II
Product Codes: IPF
Dated: February 3, 2003
Received: February 4, 2003

Dear Mr. Workman:

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 (301) 594-4659. 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/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Enclosure

510(k) Number (if known): K023230

Device Name: EchoPulse Powered Muscle Stimulator, Models 800, 400, 100

Indications for Use:

1. Relaxation of muscle spasms

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescripton Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023230