DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2001

Mr. David Richards
Vice President, Director of Regulatory Affairs
Rich-Mar Corporation
P.O. Box 879
Inola, Oklahoma 74036

Re: K012848
Trade/Device Name: Rich-Mar Winner CM[4]
Regulation Number: 890.5850, 882.5890, 890.5300, 890.5860
Regulation Name: Powered muscle stimulator
Transcutaneous electrical nerve stimulator
Ultrasonic diathermy
Ultrasound and muscle stimulator
Interferential current therapy
Regulatory Class: Class II
Product Code: IPF, GEJ, IMI, IMG, LIH
Dated: July 31, 2001
Received: August 23, 2001

Dear Mr. Richards:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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): K012848

Device Name: RICH-MAR WINNER CM4

Indications For Use:

THERAPEUTIC ULTRASOUND

Rich-Mar Ultrasound devices are indicated to produce therapeutic deep heat for the following conditions:

1) Relief of pain

2) Muscle Spasms

3) Joint contractures

But NOT for the treatment of malignancies

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Milhean

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

510(k) Number K012848

510(k) Number (if known): K012848

Device Name: RICH-MAR WINNER CM4

Indications For Use:

MICROAMPERAGE PULSED CURRENT INDICATIONS FOR TREATMENT (Microcurrent)

Microcurrent output is indicated for the following conditions:
1) Symptomatic relief of chronic, intractable pain.
2) Management of pain associated with post-traumatic or post-operative conditions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhorn

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

510(k) Number K012848

(Optional Format 3-10-98)

510(k) Number (if known): K012848

Device Name: RICH-MAR WINNER CM4

Indications For Use:

Quadpolar, Bipolar, Monophasic and Russian Waveforms

This device is indicated for the following conditions:
1) Relaxation of muscle spasms.
2) Prevention or retardation of disuse atrophy.
3) Increasing local blood circulation.
4) Muscle re-education.
5) Maintaining or increasing range of motion.
6) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

(Quadpolar Interferential and Microamperage Pulsed Current)

1) Symptomatic relief of chronic, intractable pain,
2) Management of pain associated with post-traumatic or post-operative conditions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhoan

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

510(k) Number K012848

(Optional Format 3-10-98)