



OCT 26 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sun-Rain System Corporation
c/o Mr. Yang Tien-Hsing
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun Street
Hsin-Chu City, Taipei, Taiwan ROC

Re: K011913

Trade/Device Name: Sun-Tens Palm Type R5/Compact Wireless M2 EMS Series

Regulation Number: 890.5850

Regulation Name: Powered muscle stimulator

Regulatory Class: II

Product Code: IPF

Dated: September 10, 2001

Received: October 9, 2001

Dear Mr. Tien-Hsing:

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.

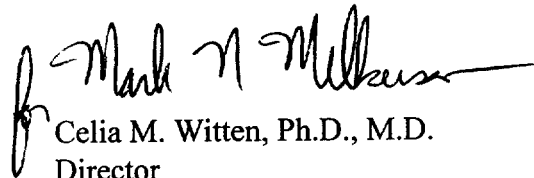
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

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

SUN-RAIN SYSTEM CORP.

F 8, NO. 125, LANE 235, BAO-CHIAO RD., HSIN-TIEN CITY, TAIPEI, TAIWAN R.O.C.

TEL: 886—2-8919-1180

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FAX: 886-2-8919-1190

WEB: www.sun-rain.com.tw

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Applicant: SUN-RAIN SYSTEM CORPORATION

510(k) Number (if known): _____

Device Name: SUN-TENS PALM TYPE R5 / COMPACT WIRELESS M2
EMS SERIES

Indications For Use:

- *Specific indications:* used to apply an electrical current to electrodes on patient's skin to function as:

Relaxation of muscle spasms;

Prevention or retardation of disuse atrophy

Muscle re-education

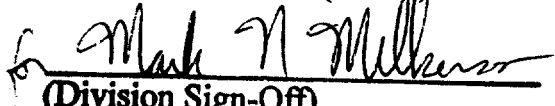
Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Maintaining or increasing range of motion.

- *Clinical settings:* The device should only be used under medical supervisions for adjunctive therapy for the treatment of medical diseases and conditions.

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

Concurrence of CDRH, office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number

K011913

Prescription Use ☒

OR 510(k) Number The — Counter — Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)