K984025

12 Appendix F: 510(k) Summary

510(k) Summary

Submitter's Information:	Christian E. Hunt Care Rehab® 1124 Dominion Ct McLean, VA 22102 Phone: 1-703-448-9644 FAX: 1-703-356-2182.
Date of preparation:	November 9, 1998
Proprietary Name:	CARE TENS™
Common Name:	TENS device
Classification Name:	Stimulator, Nerve, Transcutaneous, For Pain Relief 84GZJ; 21 CFR 882.5890.
Device Classification:	Class II
Predicate Device:	Matrix I (K895473)
Description of Device:	A portable TENS device for pain control.
Intended Use:	TENS is used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of postsurgical and posttraumatic acute pain.
Technological Comparison:	The CARE TENS has technological characteristics which are substantially equivalent to those of the predicate device, as determined by bench testing. It differs technologically only by the use of jacks and cables which comply with FDA's Final Rule "Medical Devices; Establishment of a Performance Standard for Electrode Lead Wires and Patient Cables"
Labeling Comparison:	The labeling of the CARE TENS is substantially equivalent to that of the predicate device.
Nonclinical Testing:	Bench testing demonstrated that the output characteristics or CARE TENS are substantially equivalent to that of the predicate device.
Clinical Testing:	Not applicable.
Conclusions from Testing:	The CARE TENS is substantially equivalent in electrical output to the predicate device and any differences between the devices do not pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 1999

Mr. Christian E. Hunt
President
Care Rehab and Orthopaedic Products, Inc.
P.O. Box 580
McLean, Virginia 22101

Re: K984025
Trade Name: CARE TENS™
Regulatory Class: II
Product Code: GZJ
Dated: November 9, 1998
Received: November 12, 1998

Dear Mr. Hunt:

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.

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,

for 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

4 Indications for Use

510(k) Number: K984025

Device Name: CARE TENS

Indications for Use:

TENS is used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of postsurgical and posttraumatic acute pain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984025