

FEB 11 2000

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SEIN ELECTRONICS CO., LTD.

■133-3 PYUNGCHON-DONG, DONGAN-GU, ANYANG-SHI, KYUNGKI-DO, KOREA

■TEL: ANYANG(0343)421-0389,

■FAX: (0343)421-5639

510(k) SUMMARY

"This 510(k) summary of Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

The assigned 510(k) number is

Applicant SEIN Electronics Co., Ltd.
133-3 Pyungchon-Dong, Dongan-Gu,
Anyang-Shi, Kyungki-Do, Korea
Tel: Anyang(0343)421-0389
Fax: (0343)421-5639

Contact Mr. S. H. Hwang, President
Forecare, Inc.
1540 Barclay Boulevard
Buffalo Grove, IL 60089
Tel: (847)541-8894
Fax: (847)541-8979

Date March 16, 1999

Name of Device

Proprietary Name : SE-30 TENS
Common or Usual Name : Transcutaneous Electrical Nerve Stimulator
Classification Name : Stimulator, Nerve, Transcutaneous (Pain Relief)

The SEIN SE-30 TENS device is equivalent to the Graham-Field, Inc. Micro TENS Plus transcutaneous electrical nerve stimulator.

Each product is used for the symptomatic relief of and management of long term intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

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A comparison of general specifications between the two devices is as follows:

ITEM	SEIN SE-30 TENS	GRAHAM-FIELD Micro TENS Plus
Output Channels	One output channel	Two with individual controls
Pulse Shape	Asymmetric bi-phasic & phasic rectangular shape with zero net direct current	Asymmetric bi-phasic & phasic rectangular shape with zero net direct current
Pulse Width	105-450 us programmed insert protected circuit	50-200 us variable
Pulse Rate	1-200 pulse/sec programmed	1-200 pulse/sec variable
Power Source	two alkaline AAA batteries 1.5 volt	9 volt alkaline or NiCd bat. (rechargeable option)
Maximum Voltage		
Load		
200 ohm	26 V	17 V
500 ohm	40 V	32 V
1 kohm	52 V	45 V
open	90 V	90 V
Maximum Output charge/pulse (500 ohm load for safety)	58.5 uc/pulse	14.3 uc/pulse
Maximum Output average current (500 ohm load for safety)	3.375 mA	2.3 mA
Size	70(W) x 79(H) x 17(D) mm	90(W) x 59(H) x 25(D) mm
Weight	80 grams	142 grams
Recharge Battery Option	N	Y
Battery Check	N	Y
Water Use Option	N	Y
Discriminate Polarity	Automatically Change	Required
Gel Pad	Adhesive Type	Adhesive Type
Treatment	15 min. (no daily limit)	15, 30min. (no daily limit)
MODES AVAILABLE	Mode 1... [Modulation] 1. Pulse Rate : 1-100 pps 2. Pulse Width : 220-450 usec	Constant Mode 1. Pulse Rate : 1-200 pps 2. Pulse Width : 50-200 usec
	Mode 2... [Burst] 1. Pulse Rate : 16 pulse/burst, 4b/sec 16 pulse/burst, 7b/sec 63-125 pps 2. Pulse Width : 105-450 usec	Burst Mode 1. Pulse Rate : 10 pulse/burst, 2b/sec 2. Pulse Width : 50-200 usec
	Mode 3... [Modulation] 1. Pulse Rate : 1-5 pps 2. Pulse Width : 220 usec	Modulation Mode 1. Pulse Rate : 1-200 pps 2. Pulse Width : 50-200 usec
	Mode 4... [Burst] 1. Pulse Rate : 220 pulse/burst, 1b/sec 90 pulse/burst, 1b/sec 2. Pulse Width : 220-450 usec	

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The SE-30 TENS device also was tested according to the standards of ANSI/AAMI NS4-1985 and was found to meet the requirements.

Mar. 16. 1999

Date



Tae Young Choi, President



FEB 11 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. S. H. Hwang
President
SEIN Electronics Company, Ltd.
C/O Forecare, Inc.
1540 Barclay Boulevard
Buffalo Grove, Illinois 60089

Re: K991397
Trade Name: Transcutaneous Electrical Nerve Stimulator SE-30 TENS
Regulatory Class: II
Product Code: GZJ
Dated: November 8, 1999
Received: November 18, 1999

Dear Mr. Hwang:

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

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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) 594-4595. 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 

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991397

Device Name: Transcutaneous Electrical Nerve Stimulator - SE-30 TENS

Indications For Use: the SEIN SE-30 TENS device is indicated for the symptomatic relief and management of chronic (long-term) intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

PLEASE DO NO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Melkers

for JED

(Division Sign-Off)
Division of General Restorative Devices K991397
510(k) Number _____

Prescription Use x
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)