DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2002

Dr. Dean Richards
S.H.P. International Pty. Ltd.
5/212 Glen Osmond Road
Fullarton, S.A.
Australia 5063

Re: K014273
Trade/Device Name: ACUSTIM
Regulation Name: Electro-Acupuncture
Regulatory Class: Unclassified
Product Code: BWK
Dated: March 18, 2002
Received: March 29, 2002

Dear Dr. 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): K014273

Device Name:_____

Indications For Use:

The intended use of the ACUSTIM is for use as an ELECTRO-ACUPUNCTURE DEVICE.

It can be used by a Physician administering to his patients, or by a patient.

It is a prescription device and should be used under continued medical supervision.

It does not have curative value but stimulates appropriate auricular acupuncture points.

It cannot be used transcerebrally, in the carotid sinus area or during pregnancy.

(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 K014273

(Optional Format 3-10-98)

K014273

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510(K) SUMMARY

6/12/02

Submitters Information:

S.H.P. International Pty. Ltd
5/212 Glen Osmond Road
Fullarton, S.A., 5064
Australia

Contact Person:

Dr. Dean Richards
Telephone: +61 8 8379 0700

Date Summary Prepared: August 15, 2001

Device Name:

Proprietary Name:	ACUSLIM
Common or usual name:	Portable transcutaneous electrical nerve stimulator.
Classification name:	Transcutaneous electrical nerve stimulator, Class II, 882.5890.

Legally marketed device for substantial equivalence comparison: ACUPLUS K954 334.

Description of the Device:

The device consists of a battery powered portable instrument, with a basic power pack which is connected by conducting wires to two electrodes which make contact with the skin of the outer ear of the patient.

Switching the unit on generates low level electrical pulses the strength of which are controlled by the treatment strength control button.

Technological Characteristics:

ACUSLIM uses four 1.5 volt batteries as does the ACUPLUS. Both devices have similar electrical outputs and frequency and use a rectangular waveform.

Whereas the ACUPLUS has one gold electrode and a stainless steel grounding electrode, the ACUSLIM has a positive output from a gold electrode and a negative output from an adhesive conductive electrode using the same conductive adhesive gel as is common to most TENS devices.

Performance Data:

Applicable performance testing criteria from the AAMI Standard Transcutaneous Electrical Nerve Stimulators NS4-1985, were applied.

Clinical testing results both as a pilot study in a medical practice environment, and a double blind study under the University of Adelaide General Practice Department are included in the 510k.

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