K961376

510(k) Notification for Smart-TENS: Appendix IX

SEP 12 1996

510(k) Summary of Safety and Effectiveness

This summary is submitted in compliance with the FDA interim rule 21 CFR 807.92.

(a) (1) Submitted by:

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(2) Trade name of device: Smart-TENS, Model 456

Common name: TENS

Classification name: Transcutaneous Electrical Nerve Stimulator for pain relief; §882.5890

(3) Identification of predicate or legally marketed device: Bio Tens Model: ST-601
(Skylark Device Co. Ltd., 510(k) # K912178)

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(4) Description of device:

The Smart-TENS is a compact, battery powered transcutaneous electrical nerve stimulator. It is used for the relief of chronic intractable pain by providing transcutaneous electrical pulses to areas of the body that require therapy for the indicated medical conditions. The parameters of the programs in the Smart-TENS cannot be set by the user. Two channels are available on the Smart-TENS. Each channel operates independently and if desired they may be used simultaneously. The clinician may set the prescribed program from a list of defined programs. The patient may then use this program or another available program called MultiTens which provides a pattern of sequences which allows variation and modulation on the stimulation pulse. The patient may also initiate burst mode on certain programs, cause one of the pattern of sequences in MultiTens Mode to repeat continuously, advance to the next sequence or pause the treatment session, increase or decrease the amplitude intensity of the stimulation or lock the intensity controls. Use of the device is recorded internally, allowing the clinician to determine compliance with the prescribed treatment regimen.

(5) Intended uses:

The Smart-TENS is used for transcutaneous electrical nerve stimulation for the purposes of relief of chronic intractable pain.

These uses are similar to the predicate marketed device identified in section (3) of this summary.

(6) Technological comparison

The Smart-TENS is similar the Bio Tens Model: ST-601 in that both are portable, compact battery powered TENS devices. Output for either device is suitable for the relief of chronic pain using standard skin surface electrodes. Both devices are similar in basic operational design and use the impedance of the output transformer to achieve a near net zero charge into the skin. The Smart-TENS is effectively a more user controllable device which indicates patient compliance.

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(b) (1) Non-clinical tests:

Comparisons of stimulation outputs for the Smart-TENS and the predicate Bio Tens Model: ST-601 show similar results that are suitable for TENS. To minimize potential electrical and mechanical hazards, Bio-Medical Research adheres to recognised and established industry practice and all devices are subject to final performance testing. The Smart-TENS is designed to conform to EN60601-1 (IEC 601-1) and conforms to EN 60601-1-2 (IEC 601-1-2).

(2) Clinical tests:

No clinical testing was performed.

(3) Test conclusions:

Testing of the stimulation output parameters of the Smart-TENS indicate that the device is safe, that it provides appropriate stimulation output for effective relief of chronic pain and that it performs as well as or better than the legally marketed predicate device identified in section (3) of this Summary.