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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Contact Person: Isaac Finnegan

Position/ Title: Regulatory Affairs Manager

Date of preparation: 6th June, 1997

(2) Trade name of device: NT2000

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)

(4) Description of device:

The NT2000 is a compact, battery powered transcutaneous electrical nerve and electronic muscle stimulator. Two channels are available on the NT2000. Each channel operates independently and if desired they may be used simultaneously. The clinician may set up to two prescribed programs from a list of defined programs for use by the patient. The parameters and options for two programs are variable. One option (dual program), the Rx and total treatment times may be set for all of the programs. The programmable parameters are frequency, pulse width, contraction time, relaxation time, ramp up time, ramp down time, amplitude limit and channel delay. The programmable options are synchronous or alternate mode, extended pulse or sub_pulse mode, monophasic or biphasic mode, single or dual frequency, load sensing on or off, audio off or on, trigger mode off or on and dual program off or on. The NT2000 is programmed using a detachable keypad connector called the NT2000C. The clinician may use the NT2000 with the NT2000C interlocked but it is generally designed for use without the NT2000C by the patient. The patient may use the selected program or another available program if provided. The patient may over ride the contraction/ relaxation cycle using an optional external trigger (if provided) or by using the override feature. The patient may also increase and decrease the amplitude of the stimulus. Use of the device is recorded internally, allowing the clinician to evaluate compliance with the prescribed treatment regimen.

(5) Intended uses:

The NT2000 is used for the symptomatic relief and management of chronic (long term) intractable pain and as an adjunctive treatment in the management of post surgical and post traumatic acute pain problems by providing transcutaneous electrical pulses to areas of the body that require therapy for the indicated medical conditions. This use is identical to the predicate marketed device identified in section (3) of this summary.

The NT2000 is also used for the purposes of relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and maintaining or increasing range of motion by providing electrical muscle stimulation to areas of the body that require therapy for the indicated medical conditions. These uses were previously cleared under FDA 510(k) # K933176.

(6) Technological comparison

The NT2000 is similar to the Bio Tens Model: ST-601 in that both are portable, compact battery powered TENS devices. Both devices deliver similar pulses to 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 NT2000 is effectively a more user controllable device which indicates patient compliance.

(b) (1) Non-clinical tests:

Comparisons of stimulation outputs for the NT2000 and the predicate Bio Tens Model: ST-601 show similar results. 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 NT2000 is designed and tested to the electrical requirements of IEC 601-1, the electromagnetic compatibility requirements of IEC 601-1-2. The NT2000 also conforms to AAMI/ANSI NS4 #3.2.3.2, 1985.

(2) Clinical tests:

No clinical testing was performed for the purpose of this 510(k) Premarket Notification.

(3) Test conclusions:

Testing of the stimulation output parameters of the NT2000 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Greg Shipp
Bio-Reg Associates, Inc.
Representing Bio-Medical Research Limited
14900 Sweitzer Lane, Suite 200
Laurel, Maryland 20707

FEB 27 1998

Re: K972244
Trade Name: NT2000
Regulatory Class: II
Product Code: GZJ
Dated: December 12, 1997
Received: December 15, 1997

Dear Dr. Shipp:

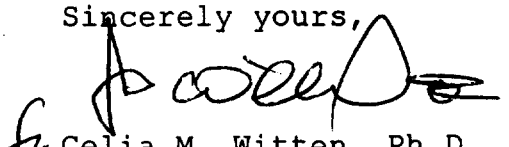
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

Indications for Use Statement

510(k) Number (if known): Not Available

Device Name: NT2000
Sponsor Name: Bio-Medical Research Ltd.

Indications for Use:

The NT2000 is indicated for:

a) Transcutaneous Electrical Nerve Stimulation (TENS) for the symptomatic relief and management of chronic (long term) intractable pain and as an adjunctive treatment in the management of post surgical and post traumatic acute pain problems.

b) Electrical Neuromuscular Stimulation for the purposes of relaxation of muscle spasm, prevention or retardation of disuse muscle atrophy, muscle re-education, increase local blood circulation, maintain or increase range of motion, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K972244

Prescription Use ☑
Over-The-Counter Use ☐