OCT 20 1999

K990787

510(k) Summary

Trio 300 Multi-Mode Electical Stimulator

Common/Classification Name: 21 CFR 882.5890, 21 CFR 890.5850

Ito Co., Ltd.
3-3-3 Toyotama-Minami
Nerima-ku, Tokyo 176-8605
JAPAN

Contact: H. Okada , Prepared: March 8, 1999

A. LEGALLY MARKETED PREDICATE DEVICES

The **Trio 300 Multi-Mode Electrical Stimulator** is a device that combines four types of electrical stimulation in one device. It has a TENS mode, an electrical muscle stimulation mode, a microcurrent mode, and a general programmable mode. Since it appears that this particular combination of modes has not been present to date in any single device, it is necessary to claim substantial equivalence to more than one predicate device. The TENS, microcurrent, and programmable modes of the **Trio 300 Multi-Mode Electrical Stimulator** are substantially equivalent to the corresponding modes of the Acutron Mentor Model 961 (K981976). The electrical muscle stimulation (EMS), TENS, and programmable modes of the **Trio 300 Multi-Mode Electrical Stimulator** are substantially equivalent to the Bio-Medical Research Model NT2000 Stimulator (K972244).

B. DEVICE DESCRIPTION

The **Trio 300 Multi-Mode Electrical Stimulator** is a small, portable, battery-powered electrical stimulator device that has four stimulation modes, (1) TENS, (2) EMS, (3) microcurrent, and (4) programmable. The device has an LED screen that serves as the interface with the user to specify options, provide messages, and display parameters. The device is supplied with an AC adaptor for line current operation.

The **Trio 300** consists of the pulse generator, A/C power adapter, and the surface electrodes.

The **Trio 300** is a dual-channel electrical stimulator with four output modes. The device is equipped with a liquid crystal display (LCD) for communication with the user. The SELECT key allows the user to scroll through the options (e.g., mode) available at a particular point and the

SET key allows the selection of the displayed option. The UP-ARROW and DOWN-ARROW keys allow the user to increase or decrease certain selected parameters.

C. INTENDED USE

The TENS mode of the **Trio 300** is indicated for the symptomatic relief of chronic intractable pain. It is also indicated for the treatment of post-traumatic and post-surgical pain. The electrical muscle stimulation (EMS) mode is indicated for 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.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Trio 300 Multi-Mode Electrical Stimulator** is a medical device, and it has the same indications for use and target population as the legally marketed predicate devices. The **Trio 300 Multi-Mode Electrical Stimulator** has the same technological characteristics as the predicate devices. This premarket notification will describe the characteristics of the **Trio 300 Multi-Mode Electrical Stimulator** in sufficient detail to assure substantial equivalence except for a few of the characteristics where performance testing was carried out (e.g., electrical safety).

E. TECHNOLOGICAL CHARACTERISTICS

The Trio 300 and one of the predicate devices all portable, battery-powered, electronic pulse generator devices with surface electrodes. The Trio 300 and both predicate devices are microprocessor-based and employ digital and analog circuits to produce the specified waveforms and levels. All employ an LCD screen as the user interface.

The electrodes that will be supplied with the **Trio 300 Multi-Mode Electrical Stimulator** are manufactured in the U.S. by Axelgaard Manufacturing Company and are currently marketed products (K970426). Two sizes are available, 2" by 2" and 2" by 3.5".

F. TESTING

Testing was carried out to assure compliance with recognized electrical safety standards. Ito has certified compliance with the EN-60601 standard for electrical safety. Testing to UL 2601 is in progress.

TUV has issued an Attestation of Conformity for the Trio 300 in regard

to the EN 60601-1-2 standard for electromagnetic compatibility.

The design qualification testing demonstrated that the Trio 300 met its design specifications.

G. CONCLUSION

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 20 1999

T. Whit Athey, Ph.D.
Senior Consultant
Representing ITO Co., Ltd.
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K990787
Trade Name: Trio 300 Multi-Mode Electrical Stimulator
Regulatory Class: II
Product Codes: IPF, GZJ
Dated: July 21, 1999
Received: July 21, 1999

Dear Dr. Athey:

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 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). 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.

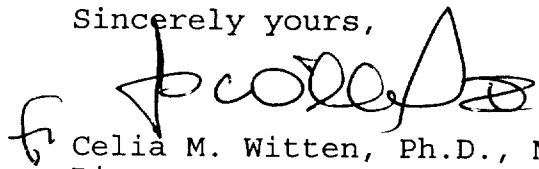
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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" (21CFR 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/dsma/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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K990787

Device Name: Trio 300 Multi-Mode Electrical Stimulator

Indications For Use:

The TENS and Microcurrent modes of the **Trio 300** are indicated for the symptomatic relief of chronic intractable pain. They are also indicated for the treatment of post-traumatic and post-surgical pain. The electrical muscle stimulation (EMS) mode is indicated for 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990787