K030254

FEB 2 6 2003

RYAN TELEMEDICINE

510(k) Summary
for
RTM1000 Interferential Stimulator

1. Sponsor

Ryan Telemedicine
1011 Brioso Drive
Suite 102
Costa Mesa, Ca 92627

Contact Person: Jim Klett
Telephone: (949) 645-4140
Fax: (949) 645-1145

Date Prepared: January 7, 2003

2. Device Name

Proprietary Name:	RTM1000 Interferential Stimulator
Common/Usual Name:	Electrical Muscle and Nerve Stimulator
Classification Names:	Interferential Current Stimulator, Powered Muscle Stimulator
Classification Panel:	Physical Medicine
Panel/Product Code:	890.5850 / IPF

3. Legally Marketed Device to Which Equivalence is Claimed

Proprietary Name:	CS3101 Interferential Stimulator
Common/Usual Name:	Electrical Muscle and Nerve Stimulator
Classification Names:	Interferential Current Stimulator, Powered Muscle Stimulator
Classification Panel:	Physical Medicine
Panel/Product Code:	890.5850 / IPF

4. Intended Use

The RTM1000 Electrotherapy Device is a multifunction device intended to be used for muscle and nerve stimulation using either of its two therapy modes, Interferential Current Stimulation and Neuromuscular Electrical Stimulation.

In the Interferential Current Mode the RTM1000 is indicated for the following conditions:

- Symptomatic relief of acute pain
- Symptomatic management and relief of chronic pain
- Adjunctive treatment for the management of post traumatic and Post-surgical pain

In the Neuromuscular Stimulation Mode, the RTM1000 is indicated for the following conditions:

- 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.

5. Device Description

The Ryan Telemedicine RTM1000 Interferential Stimulator is a battery powered (rechargeable) device intended for clinic, and outpatient use. Once prescribed by a physician it gives the clinician a variety of electrotherapy modes to treat a range of indications. The RTM1000 is designed for clinician and patient ease of use and provides safe and effective dispensing of the desired electrotherapy treatment. The RTM1000 incorporates the following features:

- Two independent stimulation channels, which provide true interferential current, neuromuscular stimulation and transcutaneous electrical nerve stimulation.
- Continuous or pulsed stimulation. Adjustable sweep and ramp times.
- Adjustable amplitude and frequency
- Four programmable therapy protocols
- Five preset therapy protocols
- Adjustable on and off times
- Pause button to allow temporary cessation of treatment and a resume button to allow the continuance of treatment. When a treatment session is paused, the timer does not countdown. Upon resumption of treatment, the timer resumes it's countdown and the amplitude (intensity) is reset to zero.
- Easy to connect, easy to handle, patient lead wire/cable assembly with a "one way" connector and color coded lead wires contribute to improved patient experience and improved therapy outcomes.
- Timed therapy sessions.
- Robust rechargeable Nickel Metal Hydride battery system with rapid recharge (85% recharge in 30 minutes – full charge in 2 hours)

6. Basis for Substantial Equivalence

The RTM1000 is substantially equivalent to the legally marketed device and is similar in design, features and function and provides the intended therapy in a safe and effective manner. Both devices offer various preprogrammed treatment protocols and the clinician or patient can choose one or more of these pre-set options. Furthermore, both allow the clinician to customize a treatment protocol for each individual patient within the parametric ranges and save the treatment into memory.

Bench testing was performed on the marketed device and the RTM1000 and the therapy output and performance characteristics for both units was very similar and consistent

7. Differences Between the Marketed Device and the RTM1000

The RTM1000 incorporates several improvements over the legally marketed device, including:

- Equal recharge time at a lower charging temperature.
- Improved safety due to the device software preventing therapy treatment while connected to wall current (recharging).
- 29% smaller size while maintaining equal output characteristics and power.
- Separate on and off buttons with easy to understand color-coding provides safer user interface.
- Improved patient lead wire/cable assembly provides easier wire management and easier electrode connections due to color-coding.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2003

Ryan Telemedicine
C/O: Mr. John So
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
Camas, WA 98607-8542

Re: K030254
Dated: February 11, 2003
Received: February 12, 2003

Trade/Device Name: Interferential Stimulator, Model RTM1000
Regulation Numbers: 21 CFR 890.5850
Regulation Names: Powered muscle stimulator
Regulatory Class: Class II
Product Codes: IPF, LIH

Dear Mr. So:

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.

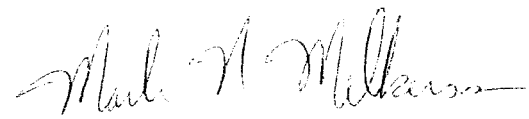
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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-. 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,



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): K030254

Device Name: Interferential Stimulator, Model RTM1000

Indications For Use:

The RTM1000 Electrotherapy device is a multifunction nerve stimulation device intended to be used for muscle and nerve stimulation using any one of its two therapy modes, Interferential Current Stimulation, Neuromuscular Electrical Stimulation.

In the Interferential Current Mode the RTM1000 is indicated for the following conditions:

- Symptomatic relief of pain
- Symptomatic management and relief of chronic pain
- Adjunctive treatment for the management of post traumatic and post-surgical pain.

In the Neuromuscular Stimulation Mode, the RTM1000 is indicated for the following conditions:

- Relaxation of muscle spasms;
- Prevention or retardation of disuse atrophy;
- Increasing local blood circulation;
- Muscle re-education;
- Immediate post surgical stimulation of calf muscle to prevent venous thrombosis; and
- Maintaining or increasing range of motion.

for Mark N Milkerson

Division Sign-Off)
Division of General, E
and Neurological Devi

510(k) Number K030254

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

Concurrence of CDRH, Office of Device Evaluation (ODE)