DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rian Corp Pty Ltd
c/o Ms. P. Ann Angel
Executive Director
2/331 Seaview Road
Henley Beach
South Australia 5022
Australia

OCT 2 6 2006

Re: k030295
Trade/Device Name: Rian Corp LTU-904 Portable Laser Therapy System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: NZY
Dated: March 9, 2006
Received: April 20, 2006

Dear Ms. Angel:

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

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), please contact the Office of Compliance at (240) 276- 0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K030295
Device Name: LTU-904 Portable Laser Therapy Unit

Indications for Use:

The LTU-904 is indicated for use as a tool as part of a therapy regime for the treatment of post mastectomy lymphedema.

Prescription Use_____X___ and/or Over –The Counter Use_____
(Part 21CFR801 Subpart D) (21 CFR 801 Subpart C)

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

Center for Devices and Radiological Health

510(k) Number K030295

510(k) SUMMARY

Riancorp Pty Ltd.'s
LTU-904 Portable Laser Therapy Unit

Submitter's and Sponsor's Name, Address, Telephone Number, Contact Person

Riancorp Pty Ltd
7 Fleet Street
Richmond
South Australia 5033

Phone: 61-8-8232 8822
Facsimile: 61-8-8232 8833

Contact Person: Ms. Patricia Ann Angel

Date Prepared

September 2006

Name of Device

LTU-904 Portable Laser Therapy Unit

Common or Usual Name

Low Level Laser Therapy Device

Classification Name

Non-heating Lamp for Adjunctive Use in Pain Therapy (21 C.F.R. §890.5500)

Predicate Devices

MicroLight Corporation of America's MicroLight 830
Acculaser, Inc.'s Acculaser Pro Low Level Laser Therapy

Indications for Use

The LTU-904 is indicated for use as a tool as part of a therapy regime for the treatment of post mastectomy lymphedema.

Technological Characteristics

The LTU-904 Laser Therapy Unit is a hand-held battery powered treatment device, is non-thermal and delivers a controlled series of 200 ns bursts of pulses of 904nm laser beam, which is in the near infrared spectrum that is invisible to the human eye.

The LTU-904 is classified as a Class I Laser according to the USA FDA 21 CFR 1040.10 and 1040.11 regulations.

Performance Data

LTU-904 for the Treatment of Post Mastectomy Lymphedema

Many patients suffer from arm swelling after breast cancer treatment. This is usually associated with radiotherapy and lymph node clearance. Surgery to the lymph nodes may interfere with lymph drainage. The surgery can cause a significant reduction in Lymphatic Transport Capacity (the ability of the system to clear this fluid). The scarring of surgery will also inhibit lymph flow through the area and inhibit regeneration of new vessels.

When Lymphatic Load exceeds (amount of fluid in the tissues waiting to be taken away) the Lymphatic Transport Capacity lymph accumulates in the tissues and lymphedema results. Lymphedema swelling often causes discomfort and feelings of heaviness, tension, loss of range of movement and is usually treated with compression and massage therapies. LTU-904 laser therapy is an additional tool for the treatment of post mastectomy lymphedema.

The Riancorp LTU-904 laser therapy unit was evaluated in a placebo controlled double blind clinical trial of post mastectomy lymphedema patients which has been published in a peer-reviewed journal. The study was conducted at Flinders Medical Centre in Adelaide, Australia, under ethics committee approval.

A total of 64 post mastectomy patients with at least 200 ml difference between their arms were enrolled in the study. The patients were randomized to receive one cycle (3 weeks) of either active or sham laser and then were evaluated 2 to 3 months later using objective and subjective measures. After the first cycle of treatment, the control patients were offered active treatment and the original treatment arm was given a second round (block) of laser therapy. These patients were again assessed 2 to 3 months after their second cycle of treatment.

Patients were assessed for extra cellular fluid (ECF), whole arm volume and tonometry (tissue hardness). Results indicated:

- **Volume** of the affected arm was reduced by a minimum of 200 mL in 31% of participants who received 2 cycles of treatment, 3 months after their second cycle of active LTU-904 therapy. In an Intent-to-Treat (ITT) analysis, where all patients lost to follow-up or with missing data were considered failures, approximately 20% of the subjects met the 200 mL criteria following their 2nd active treatment cycle. This is compared to 4% of those who received one cycle of placebo treatment.

- **ECF** was significantly reduced following 6 weeks of LTU-904 therapy, in: (1) the affected arm (immediately after the course of treatment and maintained at 1 and 3 month follow-up); (2) the trunk (immediately after the course of treatment and maintained at 1 month follow-up); and (3) the unaffected arm (immediately after treatment).

  52% of participants experienced a clinically significant decrease in ECF after 6 weeks of active laser. In contrast only 19% of people who had placebo treatment achieved the same reduction.

No adverse effects from the laser treatments were observed by the investigators. This study demonstrated that in all treatments of post mastectomy lymphedema, the LTU-904 functioned as intended.

Substantial Equivalence

The LTU-904 has no significant changes or modifications compared to the predicate products that effect safety, effectiveness, or the device's intended use of applying low level laser therapy to tissues. The following technological characteristics are the differences between the LTU-904 and predicate devices:

Laser wavelength. The LTU-904 device and the MicroLight 830 and Acculaser Pro LLLT all use laser diodes with wavelengths in the near infrared region. The difference in these wavelengths is clinically insignificant due to the closeness of the wavelengths and because these differences do not impact the depth of penetration or absorption in tissue.

1. **Laser Safety Class.** Due to the design and construction of the LTU-904 device it is a Class I Laser device according to the USA FDA 21 CFR 1040.10 and 1040.11 regulations whereas the other predicate devices are all Class 3B. This is not a significant issue due to the fact

that the LTU-904 device has a lower classification and has been validated clinically to support the device's indications for use.

2. **Maximum Laser Power.** The LTU-904 has a maximum average laser power of 5.0 mW whereas the other devices are rated at 30 mW. This is not a significant issue due to the fact the LTU-904 device has a lower maximum power and has been validated clinically to support the device's indications for use.
3. **Laser Mode of Operation.** The LTU-904 uses a pulsed output laser beam instead of a continuous wave (CW) output. The pulsing frequency is high (2.5 KHz for the low setting and 5.0 KHz for the high setting) and the pulse duration is 200 ns. Clinical data supports that this mode of operation, where high peak power (yet low average power) when delivered to the patient, achieves clinically significant results.

Compared to its predicate devices, the LTU-904 device has similar technological characteristics, principles of operation, and a similar intended use of delivering low level laser therapy to tissues. The minor technological differences between the LTU-904 and its predicate devices raise no new type issues of safety or effectiveness. Moreover, clinical performance data demonstrate that the LTU-904 is as safe and effective as its predicates. Thus, the LTU-904 is substantially equivalent.