K030226 1/2

APPENDIX C
SUMMARY OF SAFETY AND EFFICACY

FEB 1 0 2003

510(k) PREMARKET NOTIFICATION SUMMARY
(per 21 CFR 807.92)

THØR DDII 830CL3 Laser System

I. Applicant:

THØR International Ltd.
Caer Sidhe
Chiltern Road
Amersham
HP6 5PH United Kingdom
Telephone: +44 1494 433 736
Facsimile: +44 1494 431 481

Contact: James Carroll
james@thorlaser.com e-mail

Contact Person: M. Joyce Heinrich
Texas Applied Biomedical Services, Inc.
12101 Cullen Blvd., # A
Houston, Texas 77047
713 / 734-4433 telephone
713 / 734-5671 facsimile
tabs1@tabs.net e-mail

II. Device Name:

Proprietary Name:	THØR DDII 830CL3 Laser System
Common / Usual Name:	Low Level Laser System
Classification Name:	Infrared Lamp (21 CFR 890.5500)
Product Code:	NHN

III. Predicate Device

THØR DDII 830CL3 Laser System is substantially equivalent to other low level therapeutic lasers currently in commercial distribution. These predicate devices include the MicroLight Corporation of America, Inc. MicroLight 830 Laser System (K010175), Acculaser, Inc. Acculaser Pro Low Level Laser System (K020657) and the MedX LCS System (K021985). These devices were cleared for introduction into interstate commerce via the FDA's 510(k) Notification process. The Therapeutic Laser System has the same intended use as and similar technological characteristics to these predicate devices.

IV. Intended Use of the Device

The THØR DDII 830CL3 Laser System is a non-heating infrared lamp and is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

V. Description of the Device

THØR DDII 830CL3 Laser System is a handheld, non-invasive, low energy, non-heating infrared therapeutic medical laser that is intended for use as an adjunct treatment for managing the temporary relief of pain associated with Carpal Tunnel Syndrome. The THØR 830CL3 Laser System incorporates three 30 milliwatt (mW) Gallium Aluminum Arsenide (GaAlAs) laser diodes delivering a total output power of 90 milliwatts (mW) at 830 nanometer (nm) wavelength.

VI. Summary of the technical characteristics of the THØR DDII 830CL3 Laser System to the referenced predicate device.

The THØR DDII 830CL3 Laser System and the aforementioned predicate devices are non-heating infrared lamps as defined in 21 CFR 890.5500. These devices use infrared diodes to emit invisible photonic energy to tissue. The intended use is identical for all devices.

VII. Testing

Testing of the THØR DDII 830CL3 Laser System included functional performance testing and electrical safety testing.

The THØR DDII 830CL3 Laser System is manufactured to comply with the following European standards:

Medical Electrical Equipment	EN60601-1: 1993
Medical Laser Equipment	EN 60601-2-22:1996
EMC	EN60601-1-2: 1994
CE Marking Classification	IIb, Certificate No. C10151 issued by SGS
Medical Device Directive	93/42/EEC Annex II

VIII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the THØR DDII 830CL3 Laser System has the same intended uses, with similar functional and performance characteristics. The System is designed to comply with the generally accepted therapeutic laser performance specifications as an adjunctive treatment for the relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

THØR DDII 830CL3 Laser System performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2003

THOR International Ltd.
c/o M. Joyce Heinrich
Regulatory Consultant
Texas Applied Biomedical Services, Inc.
12101 A Cullen Boulevard
Houston, Texas 77047

Re: K030226
Trade Name: THOR DDII 830CL3 Laser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-Heating for Adjunctive Use in Pain Therapy
Regulatory Class: II
Product Code: NHN
Dated: January 17, 2003
Received: January 22, 2003

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket 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) 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), please contact the Office of Compliance at (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milhauser

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

APPENDIX B

STATEMENT OF INDICATIONS FOR USE

STATEMENT FOR INDICATIONS FOR USE

510(k) Number (if known): Pending K030226

Device Name: **THØR DDII 830CL3 Laser System**

Indications for Use:

The THØR DDII 830CL3 Laser System is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

(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 CFR801.109) **(Optional Format 1-2-96)**

_____
(Division Sign-Off)

510(k) Number _____

for Mark N Milhern
(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K030226