Stargate

MAR 2 6 2004

Final 510(k) Summary For Application #K032816 Dated March 23, 2004

(as required per 21CFR; §807.92)

Quantum Light Therapy System

The following modified 510k summary is in response to the issues indicated by the Food and Drug Administration in a phone conversation on March 22, 2004. This represents Stargate's Final Amended Summary.

I. Applicant ..... Stargate International, Inc.
10235 South Progress Way #7
Parker, CO 80134
Phone: 303-840-8206
Fax: 303-840-8320

II. Contact Name: ..... Robert H. Walker; CEO
rwalker@stargateinternational.com

III. Device Name

Proprietary Name ..... Quantum Light Therapy System

Common/Usual Name(s) ..... Low Level Laser Therapy (LLLT)
Therapeutic Light System

Classification Name ..... Infrared Lamp; (21CFR; §890.5500)

Product Code(s) ..... NHN

IV. Predicate Device/Substantial Equivalency

The Quantum Light Therapy System is substantially equivalent to other pulsed low level therapeutic lasers and light therapy systems currently in commercial distribution. The Quantum Light Therapy System has the same intended use and similar technological characteristics to predicate devices. It combines the clinically accepted therapeutic uses of previously FDA 510(k) approved light therapy systems currently in commercial distribution into one complete, compact, and cost-effective system.

The technological equivalence to the predicate devices is substantiated by the wavelengths and power outputs generated by the individual Quantum System applicator heads. Depending on the applicator head chosen by the clinician, the Quantum System will provide the same treatment benefits and regimens for conditions already approved by the Food and Drug Administration.

The predicate devices the Quantum System establishes equivalence to include the following:

Predicate Device	510(k) #	Manufacturer
Tuco Erchonia PL3000	K012580	Tuco Innovations
Super Nova; Accubeam	K001179	Light Force Therapy, Inc.
MedX 100 Series	K020017	MedX Electronics, Inc.

V. Intended Use of the Device

The Quantum Light Therapy System is a non-heating lamp, infrared as described under the provisions of 21 CFR §890.5500 and is indicated for:

A- Adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin using the QS-2; QS-4; and/or the QS-L applicator heads.

VI. Description of the Device

The Quantum Light Therapy System is a hand-held, non-invasive, pain therapy system which utilizes non-heating lamps consisting of both laser and light emitting diodes(LED) in three optional applicator heads. It combines the clinically accepted therapeutic treatment of numerous predicate light therapy systems currently in commercial distribution and 510(k) approved into one complete, compact, and cost-effective system.

The system consists of a basic hand-held, battery operated control unit and three optional (one-LED; two-laser) and interchangeable applicator heads which can only be used with the Quantum Light Therapy System control unit.

The three distinct applicator heads produce wavelengths that range between 609-645nm which falls within the spectrum as defined by 21 CFR §890.5500.

The two laser applicator heads produce an output power of <5mw per non-convergent beam and are classified as Class IIIa lasers. Both operate at a measured wavelength of 635nm ±1% and comply with all performance, labeling, and manufacturing standards set forth in 21CFR Part 1040. Stargate International, Inc. has filed as a registered laser manufacturer with the Food and Drug Administration.

The distinct LED applicator head produces a non coherent diffuse light source. This applicator head operates at a measured wavelength of 628nm ±3%.

VII. Summary of Technical Characteristics of the Device To Referenced Predicate Devices

The Quantum Light Therapy System and the aforementioned predicate devices use diodes to emit visible photonic energy to human tissue. The intended use of the Quantum Light Therapy System is identical to all predicate devices depending on the Stargate applicator head chosen by the clinician.

VIII. System Testing

The testing of the Quantum Light Therapy System includes functional performance, software, firmware, electrical safety, and component specification verification. This includes four-staged manufacturing testing and verification along with independent certifications by an outside independent laboratory.

The Quantum Light Therapy System is manufactured, performs, is labeled, and is tested to comply with the following standards:

- FCC Standard - 47CFR Part 15B
- All Electrical Components Utilized Are UL® Approved
- Class IIIa Laser - 21CFR Part 1040.
- IEC60825-1, Amendment 2
- IEC 60601-2-22
- EMC: IEC 60601-1-2

IX. Conclusions

In accordance with testing and comparison to the predicate devices, and pursuant to 21CFR; §890.500, the Quantum Light Therapy System has the same intended uses, with similar functional and performance characteristics.

The device meets or exceeds the design, testing, and labeling standards required by law. The Quantum Light Therapy System is manufactured and performs as intended and does not raise any new regulatory, safety, and/or clinical efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 2004

Mr. Robert H. Walker
CEO
Stargate International, Inc.
10235 South Progress Way, #7
Parker, Colorado 80134

Re: K032816
Trade/Device Name: Quantum Light Therapy 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: December 23, 2003
Received: December 29, 2003

Dear Mr. Walker:

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), 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 Miriam C. Provost

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

Indications For Use

510(k) Number (if known): K032816

Device Name: Quantum Light Therapy System

Indications For Use: The Quantum Light Therapy System is a non-heating lamp, infrared as described under the provisions of 21 CFR §890.5500 and is indicated for:

Adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin using the QS-2; QS-4; and/or the QS-L applicator heads.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032816