DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 2003

Quantum Devices, Inc.
C/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue SE
Grand Rapids, MI 49548

Re: K032229
Trade/Device Name: Quantum WARP 10 Light Delivery System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: August 20, 2003
Received: August 28, 2003

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of September 11, 2003, regarding the over-the-counter notation on your Indications for Use enclosure.

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.

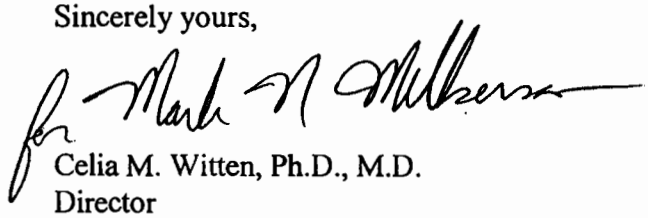
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

DEC 2 - 2003

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,



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): K032229

Device Name: Quantum WARP 10 Light Delivery System

Indications For Use:

The Quantum WARP 10 Light Delivery System is a hand held device used for the treatment of chronic pain by emitting energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

(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)

for Mark N Melkerson

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

510(k) Number K032229

(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

510(k) Number _____

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K032229

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9.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CRF 807.92.

Applicant:

Quantum Devices, Inc.
112 Orbison Street
Barneveld, WI 53507

Phone: 608-924-3000
Fax: 608-924-3007

Contact Person:

Michele Vovolka
Vantage Consulting International, Ltd.

Prepared on:

July 18, 2003

Model No./Name:

Quantum WARP 10 Light Delivery System

Classification:

Lamp, Infrared -- 89 ILY
Physical Medicine Device, 21 CRF 890.5500 (Class II)

Predicate Devices:

Light Force Therapy Inc., Super Nova - K022888
Bales Scientific Inc., Photomic Stimulator - K974468
DioMedics Inc., Pain-X-2000 Model 5700 – K982546

Description:

The Quantum WARP 10 Light Delivery System is used for applying therapy for the mitigation of chronic pain. These light delivery systems are manufactured by Quantum Devices, Inc. These devices are solid state and hand held for placement directly over the skin where the treatment is to occur.

Statement of Intended Use for Quantum WARP 10

The Quantum WARP 10 Light Delivery System is a hand held device used to emit energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where heat is indicated.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

Testing Summary

Testing for the Quantum WARP 10 Light Delivery System has been carried out to ensure that the temperature at the skin surface where the device is applied is acceptable per IEC 60601-1 Part 42.3 (UL2601-1)

Substantial Equivalence:

The Quantum WARP 10 Light Delivery System is substantially equivalent to the:

Light Force Therapy Inc., Super Nova - K022888
Bales Scientific Inc., Photomic Stimulator - K974468
DioMedics Inc., Pain-X-2000 Model 5700 – K982546

The Quantum Device, Inc. Quantum WARP 10 is substantially equivalent to these products in that it has the same intended use and similar technical characteristics. Technical characteristics comparison included power, wavelength, waveform, energy source, power supply, energy delivery, treatment time, indicated use, target population, and location for use.

Table 1

Infrared Lamp Comparisons

Company	Quantum Devices, Inc.	Light Force Therapy, Inc.	Bales Scientific, Inc.	DioMedics, Inc.
Device Name	Quantum WARP 10	Super Nova K022888	Photomic Stimulator K974468	Pain-X-2000 Model 5700 K982546
Power	30-80 mW/cm^2	3.04 mW/cm^2	95 mW/cm^2	16.25 mW/cm^2
Wavelength	Near Infrared 650 to 950nm	550nm, 620nm, and 890nm	Near Infrared 800 to 900nm	560nm, 590nm, 620nm, 670nm, and 900nm
Waveform	Constant	Pulsed	Same as Quantum Device	50% Duty Cycle
Energy Source	Multi diode dispersed over treatment area (noncoherent)	Same	Same	Same
Power Supply	8 each, 1.5AA Batteries	24 Vdc – 500 mA	115/220 Vac, 50/60Hz electric outlet	Rechargable Battery, AC Adapter
Energy Delivery	Handheld Treatment Probe	Same	Same	Same
Treatment Time	60 – 300 seconds	60 – 900 seconds	0 - 594 seconds seconds	20 – 3000 seconds
Target Size	36 mm diameter	240 mm diameter	50 mm x 50 mm	76 mm diameter
Indications for Use	To emit energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where heat is indicated.	Same	Same	Same
Target Population	Individuals suffering from chronic pain	Same	Same	Same
Location for Use	Over-the-counter use	Same	Same	Same