K 061614

Special 510(k) Summary
for
Terraquant MQ2000 v.5 and HandyRx MQ2007 Lasers

OCT - 6 2006

1. SPONSOR

Escada International, Inc.
27100 Richmond Road
Solon, Ohio 44139

Contact Person: Max Kanarsky
Telephone: 440-542 0762

Date Prepared: June 8, 2006

2. DEVICE NAME

Proprietary Name:	Terraquant MQ2000 v.5 and HandyRx MQ2007 Lasers
Common/Usual Name:	Heating lamp
Classification Name:	Heating lamp for adjunctive use in pain therapy

3. PREDICATE DEVICES

Escada Terraquant MQ 2000 Laser Therapy Device K043055

4. DEVICE DESCRIPTION

The Escada Terraquant MQ2000 Laser Therapy Device has been modified resulting in the Terraquant MQ2000 v.5 and HandyRx MQ2007 Lasers. The Terraquant MQ2000 was modified to increase the power level range for the laser from .4 to 1.4 mW to .4 to 7.5 mW and to provide the device in a hand held configuration. The proposed Terraquant MQ2000 v.5 (increased power but same configuration as Terraquant MQ2000) and the HandyRx MQ2007 (increased power level in a hand held configuration) are essentially identical in intended use and fundamental technology to the parent Terraquant MQ2000 Laser Therapy Device described in K043055. As with the original Terraquant MQ2000 system, the Terraquant MQ2000 v.5 and HandyRx MQ2007 System utilize heating lamps consisting of a laser diode, infrared diodes, and a visible red light emitting diodes (LED). It

combines the clinically accepted therapeutic treatment of numerous predicate light therapy systems currently in commercial distribution into one complete, compact system.

The parent Terraquant MQ2000 system and the Terraquant MQ2000 v.5 consist of a desktop control unit, and a hand-held emitter from which the laser and other radiances are released, and a 110 V power adaptor. The proposed HandyRx MQ2007 consists of only the handheld emitter from which the laser and other radiances are released. Both the parent and proposed device laser and light therapies release radiation with wavelengths that fall within the range as defined in 21 CFR 890.5500 for an infrared lamp.

5. INTENDED USE

The Terraquant MQ2000 v.5 and HandyRx MQ2007 Lasers are heating lamps intended for pain management with applications that include 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Terraquant MQ2000 v.5 and HandyRx MQ2007 Lasers and the parent TerraQuant MQ2000 device are substantially equivalent in intended use in that they are all heating lamps intended to provide relief to various areas of the body depending on the site of pain.

The proposed TerraQuant MQ2000 and the HandyRx MQ2007 Lasers and the parent Terraquant MQ2000 are substantially equivalent in technological characteristics in that they both consist of hand-held, heating infrared lamps that deliver low level laser energy to various anatomic areas.

During design validation, Escada performed testing on the modified hardware and firmware components to confirm that the modified Terraquant MQ 20007 and HandyRx MQ2007 Device perform as intended and is reliable. Testing was also performed to demonstrate that the HandyRx MQ2007 Device increases the temperature of the skin exposed to the device and maintains a skin temperature of 40 – 45°C (104 – 113°F) following a minimum of 10 minutes exposure to the light. The skin surface temperature study was conducted on human subjects in order to

determine if the hand-held HandyRx MQ2007 device, with the increased laser output power, increases the temperature of skin during use to the temperatures specified by FDA (40 °C/104 °F to 45 °C/113 °F). A comparison was made between test and control treatment conditions. The negative control was the opposite limb on the human subjects that were not treated with the HandyRx MQ2007. The HandyRx Laser MQ2007 achieved the minimum temperature (40 °C/104 °F) after approximately 6 minutes of exposure to the light. All units were able to maintain a temperature within the required temperature range of 40 – 45°C (104 – 113°F) for 24 minutes in all anatomic locations. Therefore, the HandyRx Laser MQ2007 qualifies as a heating lamp under the classification name Infrared lamp and product code ILY.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2006

Escada International, Inc.
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane, RAC
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K061614
Trade/Device Name: Terraquant MQ 2000 v.5 and HandyRx Laser MQ2007 Lasers
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY, GEX
Dated: September 6, 2006
Received: September 7, 2006

Dear Ms. McNamara-Cullinane:

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 (240) 276-0115. 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,

Barbara Buchmp
dcr

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Special 510(k) Number (if known): K 061614

Device Name: Terraquant MQ 2000 v.5 and HandyRx Laser MQ2007 Lasers

Indications for Use:

The Terraquant MQ2000 v.5 and HandyRx MQ2007 Lasers are non-invasive infrared lamps intended to provide topical heating. The Terraquant MQ2000 v.5 and HandyRx Laser MQ2007 Lasers are indicated for 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.

Prescription Use _____ AND/OR Over-the-Counter Use (X)
(Part 21 CFR 801 Subpart D) (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)

Barbara Buechner

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

510(k) Number K061614