K062635

510(k) Summary
Prepared August 5, 2006

Submitted by: CLARIMEDIX, Inc.
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DEC 19 2006

Product Name: Model 2200 System

Common Name: Infrared lamp

Classification: ILY; Class II; CFR 21 890.5500

Predicate Devices:

Device Name	Manufacturer	K Number
Warp 10	**Quantum Devices**	**K032229**
Spectropad (a.k.a. Restorative Products, Inc.)	**SMI (A.k.a. Anodyne Therapy System)**	**K931261**

Description of Device:
The device is indicated for use for the treatment of chronic pain by emitting energy in the 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

The system is a self-contained unit with four treatment areas.

- Popliteal treatment zone
- Calf treatment zone
- Foot treatment zone
- Heel treatment zone

Intended Use:
The device is indicated for use for the treatment of chronic pain by emitting energy in the 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

Comparison with Predicate Devices:
The submission device and the predicate devices have substantially equivalent intended use and technological specifications as shown in the tables below. The device is compliant with the standards for electrical safety and EMC, IEC 60601-1 IEC 60601-1-2 respectively.

Table 1 Comparison of Indications for Use

	Predicate Devices		Subject Device
	Quantum Warp 10 K032229	SMI Spectropad K931261 (a.k.a. Anodyne Therapy System)	CLARIMEDIX Model 2200
FDA classification	**21 CFR 890.5500 Infrared Lamp (ILY)** **a) Identification. An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating** **b) classification Class II**	**21 CFR 890.5500 Infrared Lamp (ILY)** **a) Identification. An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating** **b) classification Class II**	**21 CFR 890.5500 Infrared Lamp (ILY)** **a) The CLARIMEDIX device is indicated for use to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; 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 blood circulation where applied.** **b) classification Class II**
Intended Use	**Indicated for use 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**	**Intended for relief of minor muscle and joint pain and improvement of superficial circulation** [1]	**indicated for use for the treatment of chronic pain by emitting energy in the 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**
Intended Users	**Physical medicine health care professionals**	**Physical medicine health care professionals**	**Physical medicine health care professionals**
Intended Site of Use	**Medical health care facilities**	**Medical health care facilities**	**Medical health care facilities**

Table 2 Comparison of Technological Characteristics

	Predicate Devices		Subject Device
	Quantum Warp 10 K032229	**SMI Spectropad K931261 (a.k.a. Anodyne Therapy System)**	**CLARIMEDIX Model 2200**
Method of administration	Topical	Topical	Topical
Treatment areas	$10cm^2$	Leg, foot, arm, neck	Lower leg, foot, adjustable location
Number of zones	Not specified in product labeling	4-8 therapy pads	Four zones
Temperature at the skin surface	Not specified in labeling	Not specified in labeling	Less than 95° F
Energy source	Multidiodes dispersed over treatment zones	60 Infrared diodes per array	Multidiodes
Waveform	Constant	Not specified in labeling	Modulating
Power supply	8 each 1.5 AA batteries provides 50 doses	Not specified in labeling	24V
Safety features	Remains cool to the touch	Not specified in labeling	Remains cool to touch
Biocompatibility	Not specified in labeling	Not specified in labeling;	Biocompatible drape recommended
Configuration	Handheld	4-8 pads applied	4 zones applied
Length and width	5.55in x 2.65 in	Not specified in labeling	25.1 in. x 10.0 in.
Portable	Yes	Yes	Yes
Electrical safety	Not specified in labeling	Not specified in labeling	Compliant with IEC 60601-1
Firmware control	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CLARIMEDEX, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25TH Street, Northwest
Buffalo, Minnesota 55313

DEC 19 2006

Re: K062635
Trade/Device Name: Model 2200
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: December 6, 2006
Received: December 7, 2006

Dear Mr. Job:

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,

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

Enclosure

510(k) Number (if known):

Device Name: Model 2200

Indications For Use:

The CLARIMEDIX device is indicated for use to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; 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 blood circulation where applied.

Prescription Use____X____ OR Over-The-Counter Use _____
(Per 21CFR 801)

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

_____ Concurrence Of CDRH, Office Of Device Evaluation (ODE)

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

510(K) Number K062635