510(k) Summary

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant

Xanacare Technologies LLC
9185 East Kenyon Ave., Ste. 270
Denver, CO 80237 USA
Tel: 720-554-9262 / Fax: 720-554-9264

510(k) Correspondent

Robert N. Clark, President and Senior Consultant
Medical Device Regulatory Advisors, Inc.
13605 West 7th Ave., Golden, CO 80401 USA
Tel: 303-463-0900 / Fax: 303-558-3833

Date Prepared

August 19, 2008

Trade Name of Device

ComboCare 2000

Common Name of Device

Lamp, non-heating, for adjunctive use in pain therapy

Classification Name

Infrared Lamp

510(k) Classification

Class II

Device Description and Intended Use

The ComboCare 2000 is intended for the temporary relief of minor muscle and joint pain, promoting relaxation of muscle tissue, symptomatic relief and management of chronic intractable pain, and adjunctive relief of post-surgical or post-traumatic acute pain.

Predicate Devices

The ComboCare 2000 does not differ significantly from predicate devices in its technological characteristics, except that it combines modalities using Red LED light, infrared LED light, therapeutic vibratory massage and E-Stim or Micro-current TENS into a single package. Modalities are similarly combined in the TerraQuant device, except that the TerraQuant uses higher power laser IR diodes and does not include a vibrator. The ComboCare 2000 has technological characteristics similar to the following predicate device(s):

- K071445 Escada International, Inc. TerraQuant MQ2000 v.5 with TQ-ITENS
- K021755 Apex Medical Corp., Apex TS1211
- K061650 EMPI, EMPI Select TENS
- K041530 Excalibur Light Therapy System
- K041565 Lazr Pulsr 4x
- K050668 GRT LITE Model 8-A Light Therapy System

Summary of Technological Characteristics Compared to Predicate Devices

	ComboCare 2000	Predicate Device
Electrical Power Source	Class II Wall-Mount Battery Charger Input 100-240 VAC 50-60 Hz, 0.6A Output: 9 VDC at 2A	Equivalent to other predicate devices rated for international electrical use (i.e. 100-240 VAC 50-60 Hz).
Battery Type	4 rechargeable Size AA NiMH batteries	Equivalent to other predicate devices that use rechargeable batteries for portability.
Infrared Light	Pulsed infrared light emitting diodes (IR LED). 24 IR LEDs @ 870 nm (standard pad), 48 IR LEDs @ 870 nm (large pad).	Equivalent to other predicate devices cleared as non-heating lamps for adjunctive use in pain therapy.
Red Light	Pulsed red light emitting diodes (RED LED). 32 RED LEDs @ 640 nm (standard pad), 64 RED LEDs @ 640 nm (large pad).	Equivalent to other predicate devices cleared as non-heating lamps for adjunctive use in pain therapy
Vibratory massage	Off + 3 levels	Equivalent to other predicate therapeutic electrical massagers and vibrators.
	E-Stim TENS mode	
Maximum Output Current	Maximum peak output current (1 KΩ load) = 30 mA / Maximum peak output current (500 Ω load) = 40 mA	K021755: 0-80 mA (500 Ω load) K061650: 0-60 mA, adjustable (500 Ω load)
Maximum Output Voltage	Maximum peak output voltage (1 KΩ load) = 30 V / Maximum peak output voltage (500 Ω load) = 20 V	K021755: 40 V (500 Ω load) K061650: 0-60V (1K Ω load)
Pulse Frequency	72 pps/Hz nominal	K021755: 2-150 pps/Hz K061650: 2-150 pps/Hz
Pulse Width	200 µs	K021755: 50-300 µs K061650: 0-400 µs
	Micro-Current TENS Mode	
Maximum Output Current	Maximum peak output current (1 KΩ load) = 9.3 mA / Maximum peak output current (500 Ω load) = 14.4 mA	K021755: 0-80 mA (500 Ω load) K061650: 0-60 mA, adjustable (500 Ω load
Maximum Output Voltage	Maximum peak output voltage (1 KΩ load) = 9.3v V / Maximum peak output voltage (500 Ω load) = 7.2 V	K021755: 40 V (500 Ω load) K061650: 0-60V (1K Ω load)
Waveform	8 Hz Asymmetrical biphasic square wave	K021755: Asymmetrical biphasic square wave K061650: Asymmetrical biphasic square wave

Clinical & Non-Clinical Testing

Xanacare did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Non-clinical testing was performed in order to validate the design against the company's specified design requirements, and to assure conformance with the following voluntary design standards:

- EN 60601-1 "Medical electrical equipment – Part 1: General requirements for safety".
- EN 60601-1-2 "Medical electrical equipment – Part 1-2: General requirements for safety - Collateral Standard"
- EN 60601-2-10 "Medical electrical equipment – Part 2: Particular requirements for the safety of nerve and muscle stimulators"

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program according to standard ISO 14971.

Substantial Equivalence

Based on the above Xanacare Technologies LLC believes that the ComboCare 2000 is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2008

Xanacare Technologies, LLC.
% Medical Device Regulatory Advisors, Inc.
Mr. Robert N. Clark
President and Senior Consultant
13605 West 7th Avenue
Golden, Colorado 80401

Re: K081141
Trade/Device Name: ComboCare 2000
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief.
Regulatory Class: Class II
Product Code: GZJ, NHN, ISA
Dated: August 19, 2008
Received: August 21, 2008

Dear Mr. Clark:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

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

510(k) Number (if known): K081141

Device Name: ComboCare 2000

Indications for Use:

The ComboCare 2000 is intended for the temporary relief of minor muscle and joint pain, promoting relaxation of muscle tissue, symptomatic relief and management of chronic intractable pain, and adjunctive relief of post-surgical or post-traumatic acute pain.

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

(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 K081141