510(K) Summary K081962

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DEC 29 2008

Date prepared: November 30, 2008

1. Identification of the device: LAPEX BCS
   Regulation Number: 21 CFR 890.5500
   Regulation Name: Infrared Lamp
   Regulatory Class: II
   Product Code: ILY

2. Equivalent legally marketed devices: The LAPEX BCS is substantially equivalent to other infrared lamps currently in commercial distribution such as the THOR DDII IR lamp System (K033923), THOR International Ltd., and Vectra Genisys Laser System (Intelect XT Laser System) (K040662), Chattanooga Group. The LAPEX BCS has same intended use as and similar technological characteristics to these predicate devices.

3. Indications for use (intended use): The LAPEX BCS is intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

4. Description of the device: The LAPEX BCS has a hand-held treatment probe, is noninvasive, low level visible and infrared lamp that provides continuous heat therapy at fixed frequency. The System consists of a Drive Unit, Power Supply and controls and optional treatment probes that contain the visible and infrared radiating elements. Various Cluster Probes are available accessories with the Drive Unit. The LAPEX BCS generator operates automatic calculation of energy output in relation to set treatment parameters and the parameters(treatment time, output power delivered) can be adjusted by using key and treatment specifications and menus as well as treatment progressing are displayed on a LCD display in real time. And the LAPEX BCS generator operates simultaneous and independent management of outputs for connecting probes with laser sources of different wavelength. The LAPEX-BCS generator supplied with 2 completely independent outputs for using two treatment probes and simultaneously, even with laser sources of different wavelengths. The LCD displays operating parameters of both channels. This allows two operators to carry out laser therapy independently: just like having two separate instruments.

5. Safety and effectiveness, comparison to predicate device. Safety testing was conducted according to IEC 60601-2-22:1995 (Second Edition) Medical Electrical Equipment: Particular Requirements for the Safety of diagnostic and therapeutic laser equipment for use in conjunction with IEC 60601-1 :1988 + A1 :1991 + A2:1995 and to IEC 60601-1-2, (2001) Electromagnetic Compatibility. The device conforms to those standards. Clinical testing using thermography on 50 subjects of various ages and races (Oriental, Black, and Caucasian) a revealed that the

LAPEX BCS can generate a skin temperature 40°±0.8° for 5min and 20min respectively. Accordingly, we concluded that the LAPEX BCS can safely and effectively provide the temporary relief in pain associated with joints and muscles. Comparison to the predicates' indications for use and energy levels also supports this conclusion.

6. Substantial equivalence chart

Feature	Thor DDII IR Lamp System K033923	Vectra Genisys Laser System K040662	LAPEX BCS
Indications for use	Intended to emit energy in the Visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation and/or temporary relaxation of muscle	Vectra Genisys (Intelect XT) LASER Module and Vectra Genisys (Intelect XT) LASER Transportable Systems are indicated for topical heating for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness, relaxation of muscle, temporary relief of muscle spasms, temporary relief of minor pain and stiffness associated with arthritis	Intended to emit energy in the Visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation and/or temporary relaxation of muscle
Power Supply	Rechargeable Battery	100-240Vac, 50~60Hz	100-240Vac, 50~60Hz
LASER Class	Class IIIb According to IEC 60825-1	Class IIIb According to IEC 60825-1	Class IIIb According to IEC 60825-1
Energy Source (LASER / LED Source)	LASER(LD) / LED 1. 660nm, 30mW X 5EA LD 2. 660nm, 200mWX5EA LD 3. 660nm, 400mWX5EA LD 4. 810nm, 50mW X 5EA LD 5. 810nm, 200mWX5EA LD	LASER(LD) / LED 1. (850nm, 100mWX5EA LD) + (670nm, 10mWX4EA LED) 2. (850nm, 200mWX5EA LD) + (670nm, 10mWX4EA LED) 3. (850nm, 100mWX 3EA LD) (950nm, 15mWX3EA SLD) + (670nm, 10mWX 7EA LED)	LASER(LD) / LED 1. 658nm, 40mW X 8EA LD 2. 658nm, 40mW X 1EA LD 3. (813nm, 150mWX4EA LD) + (658nm, 40mWX4EA LD) 4. (813nm, 150mWX4EA LD) + (670nm, 10mWX4EA LED, LD)
Diode Source	GaAlAs & GaAlInP	GaAlAs & GaAlInP	GaAlAs & GaAlInP
Diode Drive Type	Continuous Wave	Continuous Wave & Modulated Continuous	Continuous Wave

7. Conclusion: After analyzing bench, electrical safety, EMC, clinical testing data, and the comparison table above, it is the conclusion of Meridian Co., Ltd. that the LAPEX BCS is as safe and effective as the predicate device has few technological differences and has no new indications for use, thus rendering it substantially equivalent to the predicate device. A laser product report showing compliance with the US Laser Safety standard has been submitted to FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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% Kamm Associates
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DEC 29 2008

Re: K081962
Trade/Device Name: LAPEX BCS
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: November 28, 2008
Received: December 1, 2008

Dear Mr. Kamm:

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) 276-0115. 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 Biometric's (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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K081962

Device Name: LAPEX BCS

Indications For Use:
The LAPEX BCS is intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

Prescription Use _X_ (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)

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

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