K080554

INAREX
INAREX CORPORATION
735-10, Ancheong-dong, Gwangsan-gu, Gwangju, Korea
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http://www.inarex.co.kr

AUG 27 2008

510(K) SUMMARY

[as required by 807.92(c)]

1. Identification of the Device:

   -Proprietary-Trade Name: "INAREX" INAREX CORPORATION
   -Classification Name: Table, Physical Therapy, Multifunction, Product Code: JFB
   -Common/Usual Name: Thermal Massage Bed
2. Equivalent legally marketed device:

   This product is similar in design and identical in function to the Ceragem-C (K040031, CERAGEM CO., LTD.), Ceragem-RH1 (K062476, CERAGEM CO., LTD.)

3. Indications for Use (intended use):

   Thermal Massage Bed (2D-LX) is a device intended to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the infrared lamps provide topical heating.

4. Description of the device:

   Thermal Massage Bed (2D-LX) is a device intended to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the infrared lamps provide topical heating for;
   - temporary relief of minor muscle and joint pain, and stiffness
   - temporary relief of minor joint pain associated with arthritis
   - temporary increase in local circulation where applied
   - Relaxation of muscles

5. Safety and Effectiveness, comparison to predicate device:

	INAREX	CERAGEM-C (K040031)	CERAGEM-RH1 (K062476)
Intended Use	Thermal Massage Bed (2D-LX) is a device intended to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the infrared lamps provide topical heating	The intended use of the CERAGEM – C Thermal Massager is to provide the user with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heating	The intended use of the CERAGEM – RH1 Thermal Massager is to provide the user with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heating

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Voltage	AC 120V	110V	AC 120V
Power	MAX 230W	MAX 200W	MAX 200W
Frequency	50Hz ~ 60Hz	60Hz	60Hz
Ambient temperature	30°C ~ 65°C	30°C ~ 65°C (86 ~ 140°F)	30°C ~ 65°C (86 ~ 140°F)
Classification	table, physical therapy, multi function (Class II), 21 CFR 890.5880	table, physical therapy, multi function (Class II), 21 CFR 890.5880	table, physical therapy, multi function (Class II), 21 CFR 890.5880

6. Testing information and Conclusion

In all material respects, the "INAREX" is substantially equivalent to Ceragem-C (K040031, CERAGEM CO., LTD.) Testing was performed according to 'Harmonized Standard'. Software testing and validation were done according to EN 60601-1-4. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2008

Inarex Corporation
% PATS Corporation
Mr. Brandon Choi
Flemington Court # 155
La Mirada, California 90638

Re: K080554
Trade Name: Inarex Thermal Massage Bed, Model 2D-LX
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function physical therapy table.
Regulatory Class: Class II
Product Code: JFB
Dated: August 22, 2008
Received: August 22, 2008

Dear Mr. Choi:

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 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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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

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Indications for Use

510(k) Number (if known):

Device Name: Thermal Massage Bed

Indications for use: "Thermal Massage Bed (2D-LX) is a device intended to provide patients with muscle relaxation therapy by delivering heat and smoothing massage. Additionally, the thermal lamps provide topical heating for:

- Temporary relief of minor muscle and joint pain, and stiffness
- Temporary relief of minor joint pain associated with arthritis
- Temporary increase in local circulation where applied
- Relaxation of muscles:

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X____ (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 K080554