Meditech
INTERNATIONAL INCORPORATED

DEC 1 8 2008

411 HORNER AVE., UNIT #1, TORONTO, ONTARIO, CANADA M8W 4W3 • TELEPHONE: (416) 251-1055 • FACSIMILE: (416) 251-2446

# 510(k) Summary of Safety and Effectiveness

K081355

**Submitter:**

Dr. Fred Kahn
President
Meditech International Inc
411 Horner Ave. Unit 1,
Toronto, Ontario, Canada M8W 4W3
Tel: 416-251-1055
Fax: 416-251-2446

**Contact:**

Dr. Fred Kahn
President
Tel: 416-251-1055
Fax: 416-251-2446

**Date:** April 30, 2008

**Classification Name: Lamp, infrared**

**Common/Usual Name: Infrared laser**

**Product Code/Regulation #: ILY/21 CFR part 890.5500**

**Proprietary Name: BIOFLEX LD-R100 Treatment head**

**Predicate Devices:**

We are making the claim that the BioFlex LD-R100 is substantial equivalent to the predicated devices listed in the chart below.

| LEGALLY MARKETED PREDICATE DEVICE | MANUFACTURE NAME | REGULATORY CLASS AND PRODUCT CODE | 510(K) REGISTRATION NUMBER |
|---|---|---|---|
| BioFlex Prescription Unit and related Treatment Heads | Meditech International Inc | Class II/ ILY | **K051875** |
| BioFlex LD-I75 and LD-I200 Treatment Heads | Meditech International Inc | Class II/ ILY | **K041885** |

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The rationale of declaring the new BioFlex LD-R100 is substantial equivalent to the above 2 predicate devices are based on the following:

- ✓ Same Indications for use: is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of the muscle tissue.
- ✓ Similar key design technical characteristics- All contain LED lasers that are applied on the surface of the human skin.
- ✓ Same/similar power density, wavelength, and optical power
- ✓ Similar size (hand held), weight, power source, and performance

**Description:**

The BIOFLEX LD-R100 Treatment head device is to be used with the Low Intensity Laser Therapy System, BioFlex Professional System & the Prescription Unit and Related Treatment Heads. These systems were cleared under 510(k) submission K023621 & K051875 respectively. The treatment head device is a Class II Low Level Laser treatment head that apply energy, which penetrates the skin surface to the underlying tissues, and triggers normal cellular functions.

**Indications for Use:**

**Is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of the muscle tissue.**

**Technological Comparison to the Predicate:**

Technologically, the **BIOFLEX LD-R100** is substantially equivalent to the listed 2 predicated devices above. The risks, safety or effectiveness and benefits for the **BIOFLEX LD-R100** are also comparable. The table of Comparison in Section 5.1 will provide additional information illustrating that the new **BIOFLEX LD-R100** is substantially equivalent to the **BioFlex Prescription Unit and related Treatment Heads** and the **BioFlex LD-I75 and LD-I200 Treatment Heads.**

**Conclusion:**

As stated above, Meditech International's conclusion is that the BioFlex LD-R100 is safe and effective and complies with the appropriate medical standards and is substantially equivalent to the above-identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2008

Meditech International Inc.
% Mr. Mark Slonchka
Director of Product Development
and Technical Services
411 Horner Avenue, Unit #1
Toronto, Ontario, Canada M8W 4W3

Re: K081355
Trade/Device Name: BIOFLEX LD-R100 Treatment Head
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: November 19, 2008
Received: November 20, 2008

Dear Mr. Slonchka:

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

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): K081355

Device Name: BIOFLEX LD-R100 Treatment Head

Indications for Use:

The BIOFLEX LD-R100 Treatment head device is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of the muscle tissue.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil A.P. Ogden for

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

**510(k) Number** K081355