K 041885

Exhibit 19
Summary of Safety & Effectiveness

FEB 2 4 2005

25 June 2004

The ***BioFlex™ LD-I75 & LD-I200 Treatment Heads*** are designed to be used only part of the ***BioFlex Professional System***. This system was cleared in K023621. This system provides a low level laser therapy and records and displays the treatment sessions. As such, *this device* is a Class II device, having Regulation Number: ***21 CFR part 890.5500. Product Code ILY.***

This summary is submitted in behalf of:

Meditech International Inc.
411 Horner Ave., Unit #1,
Etobicoke, Ontario, Canada M8W 4W3
Voice phone number-416 251 1055
Fax phone number- 416 251-2446

This summary is submitted by:

Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut, 06907
voice phone number (203) 329 2700)
fax phone number (203) 329 2345.

The ***BioFlex™ LD-I75 & LD-I200 Treatment Heads*** are **described** as a Class II Low Level Laser treatment heads that apply energy, which penetrates the skin surface to the underlying tissues, and triggers normal cellular functions that lead to a surgery-free, drug-free, and low cost benefit to the patient, the practitioner and the health care system.

The **scientific concept** on which this device is based is the principle that by stimulating a local area with low level laser to relieve pain.

The **intended use** of this device is for a trained health care professional to diagnose that specific patients would benefit from this therapy and treat patients for specific ailments using specific protocols.

The "Indications for Use" for this 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.*

This is a *prescription only* device. The labeling, instructions and user operations are designed for health care professionals.

K041577

Exhibit 19
Summary of Safety & Effectiveness

Meditech International Inc. has determined that the ***BioFlex™ LD-I75 & LD-I200 Treatment Heads*** are substantially equivalent to the performance of **three** predicate devices:

- K 033768, Optional Infrared Handpiece for CoolGlide Lasers, manufactured by Altus Medical, Inc.
- K031612, Lamp, Infrared, Alt Laser, Model Vtr 75 manufactured by Avicenna Laser Technology, Inc.
- K024179, Lamp Infrared, Palomar Lightcube, manufactured by Palomar Medical Products,

This device is different from other predicate devices in that it is part of a regiment that uses proprietary, interchangeable treatment heads to allow various protocols (and software loaded in a P.C. computer to download protocols) and record session / patient data.

A series of factory calibration tests are conducted to verify the device is accurate and calibrated (and can maintain calibration over its useful life). The ***BioFlex™ LD-I75 Treatment Head*** has benefited from design, development, testing and production procedures that conform to Quality Systems.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. ***Meditech International Inc.*** continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION:

I hereby certify this **Summary of Safety and Effectiveness** applies for the above indicated device.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 4 2005

Meditech International, Inc.
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut 06907

Re: K041885
Trade/Device Name: BioFlex™ LD-I75 & LD-I200 Treatment Heads
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: November 28, 2004
Received: December 2, 2004

Dear Mr. Keen:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
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): K 041885

Device Name: ***BioFlex™ LD-I75& LD-I200 Treatment Heads***

Indication For Use:

The ***BioFlex™ LD-I75& LD-I200 Treatment Heads*** *are 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.*

Miriam C. Provost

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

510(k) Number K041885

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