HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

7670 '03 OCT 29 A9:48

OCT 27 2003

Ref: FDA Docket No. 1998V-0817
Accession No. 9810192-02

Dr. Fred Kahn
President
Meditech International Inc.
411 Horner Avenue, Unit #1
Toronto, Ontario
Canada, M8W 4W3

Dear Dr. Kahn:

This is in response to your September 13, 2003, request for an extension of your approved variance for the BioFlex Professional Laser Therapy System for pain treatment. The correspondence has been controlled as a supplement to your report on file, Accession No. 9810192-02.

I am approving, in accordance with 21 CFR 1010.4(c)(1), the petition of Meditech International, dated September 17, 2003, for a variance from the requirements of 21 CFR 1040.10(f)(3) and 1040.10(f)(5)(ii) of the Federal performance standard for laser products to incorporate a remote interlock connector and an emission delay. This variance will allow the introduction into commerce of the BioFlex Professional Laser Therapy System manufactured by Meditech International as identified in paragraph D below under the conditions stated in paragraph F.

A. **Variance Number**

1998V-0817

B. **Effective Date**

This variance shall become effective on the date of this letter in accordance with 21 CFR 1010.4(c)(1).

C. **Termination Date**

This variance shall be terminated 5 years from the date of this letter.

98V-0817

VRA 1

D. Laser Product For Which Variance is Granted

This variance is granted for the BioFlex Professional Laser Therapy System.

E. Provisions From Which Variance is Granted

The variance is granted from provisions of 21 CFR 1040.10(f)(3) and 1040.10(f)(5)(ii) of the performance standard for laser products requiring that each Class IIIb laser product have a remote interlock connector and have a visible or audible emission indication sufficiently prior to emission to allow appropriate action to avoid exposure to laser radiation.

All other provisions of 21 CFR 1040.10 and 1040.11 remain applicable to the laser product.

F. Conditions Under Which Variance is Granted

In lieu of the requirements referred to in item E above, the following conditions shall apply to the BioFlex Professional Laser Therapy System manufactured under this variance:

1. The laser handpiece's proximity sensor shall prevent laser emission unless placed in close proximity to the desired target.

2. If the handpiece is moved away from the target the beam emission shall cease, not reemitting until placed in close proximity to a target and the Operate Button again depressed by the operator.

G. Basis for Approval of Variance

CDRH has determined, in accordance with 21 CFR 1010.4(a)(1), that the laser product, the BioFlex Professional Laser Therapy System, incorporates alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard.

As an alternate for a remote interlock connector and an emission delay the product incorporates a proximity sensor that prevents emission until the handpiece is in close proximity to a target. Since the beam does not emit unless the target is in contact and the Operate button is depressed, the proximity sensor constitutes an equivalent degree of safety as a remote interlock connector and an emission delay.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

> ``This product is in conformity with performance standards for laser products under 21 CFR 1040, except with respect to those characteristics authorized by Variance Number 1998V-0817 effective October 7, 1998.''

This variance action is available for public disclosure in the Dockets Management Branch, FDA, and a notice of availability will be published in the FEDERAL REGISTER. The variance will remain in effect until the termination date unless the variance is amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: FDA Dockets Management, Docket No. 1998V-0817