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18 May 2000

Director
Dockets Management Branch (HFA-305)
Rm. 1061
5630 Fishers Lane
Rockville MD 20852
USA

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Dear Sir,

RE: Medi-laze Smart Laser Product Report
Accession number 9910808

Please find enclosed three copies of documents sent to:

Department of Health & Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Yours faithfully,



William Reinhold

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VARI

VARIANCE APPLICATION (Subject To 21 CFR 1010-4)

DESCRIPTION OF THE PRODUCT AND ITS INTENDED USE.

The Smart Laser portable handheld laser device is designed to deliver precise dosages of laser energy for treatment of musculo-skeletal injuries, and is suitable for use by physiotherapists, chiropractors, sports medicine therapists, beauty therapists, acupuncturists, and nursing homes.

HOW COMPLIANCE WITH THE STANDARD WOULD BE INAPPROPRIATE.

The application relates to remote interlock connector requirement in 21 CFR 1040-10 (f)(3).

The remote interlock switch (grip safety switch) on the laser handpiece is not intended to be connected to a remote barrier interlock, emergency stop switch or similar device, because the instrument will almost always be used in areas where these facilities are not available.

One typical example that illustrates the point is the Southport Golden Age Retirement Home where our laser equipment is carried from bed to bed alleviating tissue injuries on 150 elderly incapacitated patients on a daily basis. It is totally impractical to move the patients to a central treatment room where a remote barrier switch, emergency stop switch or similar device may be available. Therefore, the remote interlock facility required by regulation and provided on the equipment must for practical purposes be self-contained.

HOW WE PROPOSE TO DEVIATE FROM THE REQUIREMENT.

The Smart Laser incorporates a tried and proven, equally safe and effective system that we contend satisfies the technical requirements and spirit of the regulations.

A remote interlock switch is integrated into the laser handpiece, which must be connected to the process controller to provide laser operation. Consequently, the remote interlock connector is integrated with the handpiece cable connector, the remote interlock being one wire of six in the handpiece cable.

Functionally, the operator must hold the remote interlock switch closed to move the system from "standby" to "ready" condition. Once in the ready condition, the remote start switch is pressed to initiate laser operation. The remote interlock switch requires constant pro-active attention of the operator. A momentary release of the remote interlock switch immediately stops laser irradiation and returns system to the standby state. Under no circumstances can laser irradiation occur without the remote interlock switch being depressed.

Please refer the operation manual included in the original application for a thorough illustrated description of system operation.

ADVANTAGES DERIVED FROM DEVIATION.

The Smart Laser provides an equivalent remote interlock that replicates the static controls found in a theatre environment contemplated by the regulations, while being a self-contained portable device providing the flexibility of laser treatment in any location. The advantages to the patient of being treated in a less formal clinical environment or at home are considerable.

HOW ALTERNATIVE MEANS OF RADIATION PROTECTION IS PROVIDED.

Laser irradiation occurs only when remote interlock switch is closed. Momentary release of remote interlock switch immediately stops laser irradiation.

OTHER INFORMATION.

Testing and Certification Australia (a NATA accredited testing laboratory) determined that the Smart Laser satisfied the international standards for remote interlock connector set out in IEC 601-2-22:1995. A copy of Testing and Certification Australia report number 76524 has been lodged with the FDA (refer to page 12).

PERIOD OF TIME DESIRED THAT THE VARIANCE BE IN EFFECT.

We request that the variation be permitted for the life of the present model.

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