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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

March 29, 2001

Ref:OC:I1-1897

Accession Number: 0110370-00

via FEDERAL EXPRESS and
Fax (630) 978-0677 and
011-86-21-52827988

Scott Sinner, President
Millennium Medical Systems, Inc.
840 Amlt Ct. #1212
Aurora, Illinois 60504

President
Shanghai Wonderful Opto-Electrics Tech, Co., Ltd.
2-3F, No. 37, Railway Station Village
Shanghai 200333
CHINA

Gentlemen:

This letter is written to advise you of items of noncompliance with the Federal regulations and performance standard encountered during review of the product report of on the Shanghai Wonderful Opto-Electrics Tech. Co., Ltd., Millennium brand, models ML015--CA and ML025--CA veterinary surgical CO₂ laser systems. The report is unclear and in many places incomplete. Therefore, this compilation should not be considered to include all of the possible failures to comply.

1. 21 CFR 1005.25. Designation of U.S. agent. The manufacturer has not designated a permanent resident United States agent in accordance with this regulation.
2. 21 CFR 1010.2. Certification. Based on the information in the product report, the systems apparently lack the certification labels required by this regulation. However, in your affirmation in B.1 of the Form FDA 2877, you have stated that the systems are certified. The manufacturer's report incorrectly stated that this requirement is not applicable. In your phone conversation on March 28, 2001, you stated that the manufacturer had faxed to you a certification of conformance to IEC 60601-2-22. However, this is not the certification required by this regulation.
3. 21 CFR 1040.10(f)(4). Key Switch. Item 7.6.3 states that the key is removable in the ON position. This is in violation of this requirement.
4. 21 CFR 1040.10(f)(6). Beam attenuator. The products lack beam attenuators. Furthermore, the manufacturer has not requested approval of an alternate means of providing equivalent safety.
5. 21 CFR 1040.10(f)(10). Manual reset. The products lack a means to prevent automatic resumption of emission following an interruption by safety interlock or upon restoration of electrical power after an outage.

6. 21 CFR 1040.10(h)(1) and 1040.10(h)(2). User and service information.

The Operating Instructions and Service Manual for the model ML015—CA lacks:

- Precautions to avoid unnecessary exposure,
- Reproductions and locations of required warning labels, and
- The required statement, “Caution – use of controls...”

The Operating Instructions and Service Manual for the model ML025—CA lacks reproductions and locations of required warning labels.

The manuals for both models include clear implications that the products are intended for use in clinical procedures involving human patients. Failure to remove these implied claims will result in the products being misbranded and adulterated medical devices and subject to penalties under the Federal Food, Drug and Cosmetic Act.

7. 21 CFR 1040.10(h)(1). Purchasing information. The promotional sheet “CO₂ Laser Surgical System brief introduction” lacks a reproduction of the warning logotype label as required. We also believe that the listing of the applications for the products clearly imply promote the use of the products in clinical procedures involving human patients. Failure to remove these implied claims will result in the products being misbranded and adulterated medical devices and subject to penalties under the Federal Food, Drug and Cosmetic Act.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits the importation of laser products that are not certified or do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 working days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been imported into and distributed in the United States. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

- a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
- b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

The following failure to comply with the regulations regarding testing and record keeping was observed:

21 CFR 1002.30 and 1010.2(a)(2). The Inspection Records for both models fail to include specific checks for the presence of and functionality of all required controls, indicators and labels on the products.

The above paragraphs apply to those units that have been previously imported and distributed. With respect to those units now in imports detention, you must submit a Form FDA 766 to the FDA Chicago District Imports Office with your plan to bring these units into compliance with the Federal Standard. The regulations addressing these procedures are described on page 2 of the FORM FDA 2877 and in 21 CFR 1005.21 and 1005.22.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to: Director, Compliance Branch, Chicago District Office, Food and Drug Administration, 1000 Tower Lane, Suite 190, Bensenville, IL 60106.

The product report included many items that also need to be addressed:

1. Item 3.2 of the report indicated that the identification label was in attachment 1. The figure in this attachment was totally black and illegible. Provide a legible copy.
2. Item 3.5 indicated that a copy of the aperture label was in attachment 3. There was no attachment 3. There was an attachment 3.1 that did not contain the information required in this label.
3. Item 4.2 referenced attachment 6. There was no attachment so marked. However, we believe that this is the "CO₂ Laser Surgical System brief introduction" that was addressed above.
4. The response in item 7.2.1 confuses protective housing, safety interlock and key switch. Resubmit the entire item 7.2 paying attention to both the questions in the item and the requirements of the standard.
5. Attachment 2.1 seems to be without reference in the report. This sign or label contains wording that is not in agreement with any specific requirement. Please explain.

Please submit responses to these questions within 30 days of the date of this letter. Send these responses to: Center for Devices and Radiological Health, Attn: Electronic Product Reports (HFZ-342), 9200 Corporate Boulevard, Rockville, MD 50850, USA. Clearly mark your submission as a supplement to accession number 0110370. If you have further questions on these requirements, please contact Jerome Dennis of the Electronic Products Branch at (301) 594-4654 or Corinne Tylka of the General Surgery Devices Branch at (301) 594-4595.

Sincerely yours,

A handwritten signature in black ink that reads "Christy Foreman". The signature is written in a cursive, slightly slanted style.

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health