



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dolly Rotter, President
Mogen Circumcision Instruments, Ltd.
437 Crown Street
Brooklyn, NY 11225

February 3, 2000

Ref: NYK-2000-29

Dear Ms. Rotter:

During an inspection of your firm located at the above address, on December 6 and 8, 1999, our investigator determined that your firm imports and markets circumcision clamps. Circumcision clamps are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act ("the Act").

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820.198(a).
2. Failure to promptly review, evaluate and investigate any complaint that represents an event that must be reported to the Food and Drug Administration under the Medical Device Reporting regulations (21 CFR 803 and 804) as required by 21 CFR 820.198(d). For example, your firm received an October 15, 1996 MedWatch report from [REDACTED], a July 1, 1997 MedWatch report from [REDACTED], and a July 10, 1998 MedWatch report from [REDACTED]. Each report describes an adverse event involving your marketed circumcision clamp that resulted in serious injury requiring medical intervention. There were no records of any investigations of these complaints as required by 21 CFR 820.198(e).

Additionally, the above-stated inspection revealed that these devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to submit information

to the Food and Drug Administration ("FDA") as required by the Medical Device Reporting ("MDR") regulations, as specified in Title 21, Code of Federal Regulations, Part 804. Specifically, you failed to submit MDR reports to FDA, with copies of such reports to the foreign manufacturer, after receiving information that reasonably suggests that your marketed devices may have contributed to serious injuries as required by 21 CFR 804.25(a)(2). Your firm received an October 15, 1996 MedWatch report from [REDACTED], a July 1, 1997 MedWatch report from [REDACTED], and a July 10, 1998 MedWatch report from [REDACTED]. Each report describes an MDR reportable adverse event involving your marketed circumcision clamp that resulted in serious injury requiring medical intervention. These events should have been reported to the FDA and foreign manufacturer as serious injuries. Further, your firm failed to maintain and implement written MDR procedures as required by 21 CFR 804.34.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued to you at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and/or quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Mogen Circumcision Instruments, Ltd.
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Your response should be sent to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433 (Tel. 718/340-7000 ext. 5582).

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda J. Holman". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Brenda J. Holman
District Director

Enclosures: Federal Regulations 21 CFR 820.198 and 804
"Medical Device Reporting: An Overview"
"Medical Device Reporting for Distributors"