



June 9, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-21-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jeff Jaffary, President
Medco Instruments, Inc.
4500 W. 137th Street
Crestwood, IL 60445

Dear Mr. Jaffary:

During the inspection of your firm from January 11 to February 8, 2000, Investigators Patricia McIlroy and Norman Brown determined your firm manufactures circumcision clamps. Circumcision clamps are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that your firm's circumcision clamps are misbranded within the meaning of Section 502(t)(2) in that procedures required to be implemented and maintained, and information required to be submitted, were not submitted to the FDA, as per Title 21, Code of Federal Regulations (CFR), Part 803, Medical Device Reporting (MDR). For example:

- Failure to develop, implement and maintain written MDR procedures as required by 21 CFR 803.17.
- Failure to establish and maintain MDR event files as required by 21 CFR 803.18 in that the firm does not have adequate MDR event files. Medco could not provide copies of failure analysis of the defective clamps, results of laboratory tests, and could not produce all documentation of the firm's deliberations and decision making process used to determine if a device-related death, serious injury, or malfunction was or was not reportable per 803.18(b)(1)(i).
- Failure to investigate and evaluate the cause of MDR reportable events as required by 21 CFR Part 803.50(b)(2) in that Medco did not conduct adequate investigations to determine the cause of device related injuries and malfunctions. Medco is responsible for conducting an investigation of each event regardless of whether defective clamps are returned, and/or user error is suspected. Medco is required to report MDR reportable events, even if caused by user error.

- Failure to submit reports as required by 21 CFR 803.50(a)(1) and (2), after receiving information that reasonably suggests that one of your marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and such device or similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. For example, the following events should have been reported:
 - One incident occurred on May 20, 1999, involving an infant who experienced a partial and less than circumferential incision as a result of the malfunction of a Medco size 1.1 cm circumcission clamp. The patient required surgery under general anesthesia to correct the partial circumcission.
 - ■■■ babies suffered injuries in the month before January 21, 1999, during circumcission. The complainant reported the clamp seemed to be too large and had rough edges. ■■■ of the babies required sutures to control bleeding. The incidents involved a Medco size 1.3 cm circumcission clamp.
 - One patient injury occurred on June 18, 1997, involving a Medco size 1.3 cm circumcission clamp. This incident was reported as an MDR event by the user facility.
 - One patient injury occurred on April 30, 1997, when the circumcission bell component tore the patient's foreskin and two stitches were required to stop bleeding. This incident involved a Medco size 1.1 cm circumcission clamp.
 - One incident occurred on January 1, 1997, involving a day-old patient that experienced bleeding after the circumcission clamp malfunctioned. Sutures were required to control bleeding. This incident involved a Medco size 1.3 cm circumcission clamp.
 - One incident occurred on December 10, 1996, involving a baby that bled after use of Medco size 1.3 cm circumcission clamp. The complainant reported that the clamp was too tight and the foreskin would not fit over the clamp.
 - One patient injury occurred on October 19, 1996, when the foreskin slipped out of a Medco size 1.3 cm circumcission clamp before hemostasis had occurred in the foreskin. The patient required sutures.
 - One patient injury occurred on October 3, 1996, when a circumcission clamp malfunctioned and the patient required sutures.

You are required to submit a written MDR report for each of the above listed incidents within 15 working days of the receipt of this letter. The MDR Reports should reference this Warning Letter and be directed to:

Food and Drug Administration
Reporting Systems Monitoring Branch (HFZ-533)
Attn: Ms. Victoria A. Schmid
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

The Corrections and Removals regulation requires manufacturers, importers, and distributors to report promptly to FDA corrections or removals of devices undertaken to reduce risk to health within 10 working days. Your firm's circumcision clamps are misbranded within the meaning of Section 502(t) in that your firm failed to submit information to the FDA required by 21 CFR 806, Medical Device Corrections and Removals. For example, your firm failed to submit written reports notifying FDA of removals of circumcision clamps from dealer's shelves or end users. For example, a removal of defective circumcision clamps occurred as evidenced by your fax to a customer, dated February 24, 1999, that states, "We have removed and isolated all defective clamps and that should prevent such complaints." Your firm received complaints of these circumcision clamps involving serious injuries. Our investigators observed a pallet containing ■ returned defective circumcision clamps in an isolated area of your facility.

You are required to submit a report of all corrections and removals to the FDA, within 15 working days of the receipt of this letter, of which your firm has conducted since May 18, 1998. Please send your report to our office and address it Ms. Kathleen E. Haas, Recall & Customer Complaint Coordinator.

The Act requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you submitted a premarket notification submission [510(k)] before you began offering circumcision clamps for commercial distribution. This was confirmed during the inspection when the FDA investigator determined that your firm had not submitted such a premarket notification submission for these products, and that you were marketing and distributing the circumcision clamps as a finished device. Because you do not have marketing clearance from FDA, your distribution of these products is in violation of law. In legal terms, your product is adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

Your firm's circumcision clamps are also misbranded under Section 502(b) of the Act in that the device is in package form and fails to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

In addition, this 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/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to investigate complaints involving the possible failure of a device to meet any of its specifications or to maintain documentation of why no investigation was necessary. Failure to evaluate each complaint to determine if a Medical Device Report (MDR) is necessary. For example, the inspection revealed your firm had no documentation to show that the firm evaluated and investigated to determine the causes of the following complaints:

99-001249 – 2/15/99 1.3 Clamp – Bell too big, clamp does not work properly
98-005262 – 6/22/98 1.3 Clamp – Bell is smaller than plate
97-003093 – 5/21/97 1.1 Clamp – Clamp does not stay stable in use
97-000513 – 1/27/97 1.3 Clamp – Broken Bell

2. Failure to establish and maintain procedures for implementing corrective and preventive action including: analyzing complaints and returned product to identify existing and potential causes of non-conforming product, investigating the cause of non-conforming product, and receiving, reviewing, and evaluating complaints by a formally designated unit.
3. Failure to maintain a complete device master record for the circumcision clamp. For example, the device master record for these devices did not include specifications for the bottom plate of the circumcision clamp or labeling specifications.
4. Failure to establish procedures to ensure that digital calipers used for finished product inspection are routinely calibrated, inspected, and maintained.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. 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 closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine that your systems caused the 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 requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

We acknowledge the receipt of your firm's response, dated February 29, 2000, to our Investigator's FDA-483. We do not consider your response to be adequate because your firm did not submit an estimated date of completion for the corrective actions related to the following FDA-483 observations: #1, #2, #3, #4, and #6. We ask that your response to this letter provide the estimated completion dates for these corrective actions. Also, please provide an update regarding the progress of your firm's corrective actions.

We request that you 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.

Your response should be sent to Michael Lang, Compliance Officer. If you have any questions regarding this letter, please contact Mr. Lang at (312) 353-5863 x171.

Sincerely,

\s\
Raymond V. Mlecko
District Director