



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

g1598d

One Montvale Avenue
Stoneham, Massachusetts 02180
TEL 781.279.1675
FAX 781.279.1742

July 25, 2001

WARNING LETTER

NWE-32-01W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. A. Thomas Bender
President and Chief Executive Officer
The Cooper Companies, Inc.
21062 Bake Parkway
Suite 200
Lakeforest, CA 92630

Dear Mr. Bender:

An inspection of your facility located at 15 Forest Parkway, Shelton, CT was initiated by Food and Drug Administration (FDA) Investigator Edward Janik on March 13, 2001 and completed on March 16, 2001. This inspection confirmed that your firm manufactures the HUMI® Harris-Kronner Uterine Manipulator-Injector. This product is a medical device, as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that this device is *misbranded* within the meaning of Section 502(t)(2) of the Act, in that your firm failed to furnish material or information required by the Medical Device Reporting (MDR) Regulation, as specified in 21 CFR Part 803. For example:

- ▶ According to your own records, since 1999 there have been at least 20 complaints reported to your establishment concerning breakage of the distal tip of the HUMI® device during use (while in the patient). Only one of these complaints (CooperSurgical Complaint No. 0100-004) was ever filed with the agency, as required under 21 CFR § 803.50(a)(1) of the MDR Regulation.

The removal of the broken piece of the device from the patient—an event that necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure—is reportable as a serious injury under Part 803.

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 the regulations. The specific violations noted in this letter and the Form FDA 483 issued at the close of the inspection may be indicative of serious underlying problems in your establishment's Quality System. You are responsible for investigating and determining the causes of the violations identified by the FDA. You must also promptly initiate permanent corrective and preventive action on your Quality System.

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.

We acknowledge the receipt of the letter from Nicholas Pichotta, President and CEO, dated March 30, 2001 responding to our investigator's inspectional observations (Form FDA 483), as well as the letter dated April 11, 2001 from Thomas G. Williams, Director of Quality Assurance and Regulatory Affairs, which included copies of additional FDA Forms 3500A (medical device reports) covering incidents of tip breakage. If there are any as yet unreported instances of tip breakage, those submissions should now be made. In addition, we acknowledge the receipt of Mr. Williams' April 20, 2001 letter dealing with the corrective action that has been taken with regard to the HUMI® device.

Finally, we have received the latest correspondence from John Chapman, Regulatory Affairs Manager, dated July 18, 2001. As is discussed above, removal of a broken piece or pieces of this device from a patient are reportable events.

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

Please notify this office within fifteen (15) working days of the 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 system 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.

If you have any questions concerning this matter, please contact Mark Lookabaugh, Compliance Officer at **781.279.1675 x1718**.

Your response should be sent to:

Mark Lookabaugh
Compliance Officer
U.S. Food and Drug Administration
One Montvale Avenue, 4th Floor
Stoneham, MA 02180

Sincerely,



Gail T. Costello
Director
New England District

cc:

John Chapman
Regulatory Affairs Manager
CooperSurgical
15 Forest Parkway
Shelton, CT 06484

Thomas Williams
Director of Quality Assurance and
Regulatory Affairs
CooperSurgical
15 Forest Parkway
Shelton, CT 06484

Nicholas Pichotta
President and Chief Executive Officer
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