



OCT 8 2004

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

FEDERAL EXPRESS

Mr. Douglas Cartmell
Owner
Sterex International Limited
174 Kings Road
Tyseley, Birmingham, United Kingdom
B11 2AP

Dear Mr. Cartmell:

During an inspection of your firm located in Birmingham, United Kingdom, on June 7, 2004 through June 10, 2004, our investigator determined that your firm manufactures epilator high frequency needles. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)).

This inspection revealed that these devices appear to be adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to validate with a high degree of assurance and approved according to established procedures, a process where the results cannot be fully verified by subsequent inspection and test; as required by 21 CFR 820.75(a). For example:
 - a. The manufacturing process for the epilator high frequency needles has not been validated.

- b. Manufacturing equipment, including [REDACTED] needle production machines, packaging equipment, and a computerized visual inspection system have not been validated.
2. Failure to analyze processes, work operations, and other sources of quality data to identify existing and potential causes of nonconforming product, as required by 21 CFR 820.100(a)(1); failure to investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2); and failure to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3). For example, there were no investigations into product failures that exceeded the specified failure ratio of [REDACTED] for needle Machine [REDACTED] on the following dates: 19-5-4 ([REDACTED]), 27-5-4 ([REDACTED]), and 16-4-4 ([REDACTED]).
3. Failure to evaluate nonconformances to determine the need for an investigation and notification of the persons or organizations responsible for the nonconformance, as required by 21 CFR 820.90(a). For example, [REDACTED] batch production records of [REDACTED] reviewed [REDACTED] revealed that needles manufactured from [REDACTED] through [REDACTED] exceeded the acceptable failure ratio range of [REDACTED] and no evaluation was conducted or documented to determine the need for an investigation.
4. Failure to review associated data and documentation before release for distribution of the finished device, as required by 21 CFR 820.80(d)(2); failure to authorize the release of finished devices by the signature of a designated individual(s) before release for distribution, as required by 21 CFR 820.80(d)(3); and failure to date the authorization for release of the finished devices prior to distribution, as required by 21 CFR 820.80(d)(4). For example, batch production records reviewed from [REDACTED] through [REDACTED] were not signed or dated as being approved prior to distribution of the finished devices.

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This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed. Section 801(a) of the Act (21 U.S.C. § 381(a)).

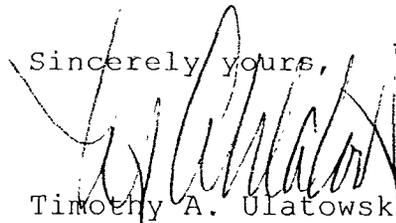
Please notify this office in writing within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Peggy C. Mayo.

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If you need help in understanding the contents of this letter, please contact Thomas C. Knott, Branch Chief, at the above address or Betty Collins, Division Director at (301) 594-4611 or FAX (301) 594-4638.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski". The signature is written in a cursive style with a large initial "T" and "U".

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health