



WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jan P. Jorens
Vice President
Orthoton BV
Avelingenwest 27c
Gorinchem, Netherlands

JUN 29 2004

Dear Mr. Jorens:

During an inspection of your establishment located in Gorinchem, Netherlands, on March 1-2, 2004, our Investigator determined that your firm manufactures the T-Gear cervical headgear traction application for orthodontic patients. T-Gear is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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 establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR § 820.30. Specifically, the investigator asked for your firm's design control procedure and the response from your firm was that there are no written design or change control procedures.
2. Failure to establish and maintain procedures to control all documents that are required by the Quality System regulation, as required by 21 CFR § 820.40. Specifically, the investigator asked to review your firm's document change control procedure to approve and document all device and process specification changes, and the response from your firm was there is no document change control procedure.

3. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR § 820.100(a). Specifically, the investigator determined that your firm has no written procedure to include requirements for the following:
 - (a) Analyzing processes, work operations, complaints, returned product and other sources of quality data to identify existing and potential causes of nonconforming product;
 - (b) Investigating the cause of nonconformities relating to product, processes, and the quality system;
 - (c) Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems;
 - (d) Verifying or validating the CAPA to ensure that such action is effective and does not adversely affect the finished device;
 - (e) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
 - (f) Submitting relevant information on identified quality problems and CAPA for management review.
4. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR § 820.198(a). Specifically, the investigator asked to review your firm's complaint handling procedure and the response from your firm was that there is no complaint handling procedure.
5. Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization, as required by 21 CFR § 820.20. Specifically, the investigator asked for your firm's quality policy and procedures and the response from your firm was that there are no written quality policy and procedures.

The above-stated inspection also revealed that your device is misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish material or information required by or under section 519 respecting the device and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. Your firm failed to develop, maintain, and implement written MDR procedures, as required by 21 CFR § 803.17(a)(1). Specifically, the

Investigator asked to review your firm's MDR procedure and the response from your firm was that there isn't a written MDR procedure.

This letter is not intended to be an all-inclusive list of violations 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 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.

Given the serious nature of these violations of the Act, the T-Gear device manufactured by your firm that is imported or offered for import is subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that it appears to be adulterated. As a result, FDA may take steps to refuse this product, known as "detained without physical examination," until these violations are corrected.

In order to remove the device from detention, you should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you if your response is adequate, and we may need to re-inspect your facility to verify that the appropriate corrections have been made. In addition, U.S. 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 government contracts.

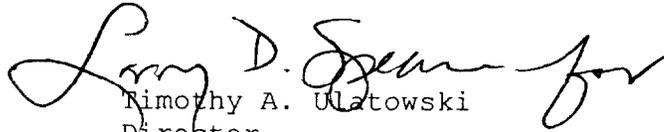
Please notify this office in writing within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include 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. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A, Dental, ENT, & Ophthalmic Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Mr. Ernest N. Smith.

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If you need help in understanding the contents of this letter, please contact Mr. Smith at the above address or at (301) 594-4613 or FAX (301) 594-4638.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Timothy A. Ulatowski".

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