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JUN 29 2004

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

FEDERAL EXPRESS

Mr. Paul Pedersen
Plant Manager
John Sjoding Ab (K.A. Rasmussen a.s.)
Strandvn. 165
N-2326
Hamar, Norway

Dear Mr. Pedersen:

During an inspection of your firm located in Hamar, Norway on February 9, 2004 through February 12, 2004, our investigator determined that your firm manufactures dental endosseous implants and attachments. 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 establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, as required by 21 CFR 820.72(a). For example, your written procedures (Document Numbers O-ATT-020 and O-ATT-021 dated June 22, 2000) require that equipment be calibrated two times a year. The following equipment has not been calibrated or checked two times a year: the _____, machines / _____, the _____ test equipment numbered _____; the _____ Machine _____, the digital meter labeled _____ used to enter the "material diameter" on the _____; and the _____ used to measure the _____. Also, the _____ Machine used to test the yield strength, ultimate tensile strength, and elongation on the "_____" has not been calibrated. The next calibration date was supposed to have been January 28, 2004.

2. Failure to document the equipment identification, calibration dates, the individual performing each calibration, and the next calibration date, as required by 21 CFR 820.72(b)(2). For example, the calibration data sheet dated August 26, 2003, for the spectrophotometer _____ used to analyze other metals was not signed and dated by the individual who performed the calibration and had no specified test value for the "Std. Dev. Sample Units" for _____.
3. Failure to review and evaluate, and investigate any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications, as required by 21 CFR 820.198(c). For example, a complaint received on October 23, 2003, and involving lot number 0746A-03 (Dental Attachment, Product Number 11702) has not been investigated.
4. Failure to make available documents established to meet document control requirements at all locations for which they are designated, used, or otherwise necessary, and to promptly remove all obsolete documents from all points of use or otherwise prevented from unintended use, as required by 21 CFR 820.40(a). For example, on February 9, 2004, the K.A. Rasmussen a.s. Document Number O-PM-015 Revision 1.01 dated September 18, 2004, had various handwritten changes. These handwritten changes did not include the signature of the approving official, the approval date, and when the change became effective. The document with the various handwritten changes was posted in the casting room and was being used by the line employees to enter process parameters for the _____ Machine.
5. Failure to have changes in documents reviewed and approved by an individual in the same function or organization that performed the original review and approval, as required by 21 CFR 820.40(b). For example, on October 16, 2003, the K.A. Rasmussen a.s. Document Number O-PM-015 Revision 1.01 dated September 18, 2001, used to enter parameters for the _____ Machine was changed in the electronic record system from the original written version. The electronic record did not include when the changes became effective or a new revision number and date. According to employees, the October 16, 2003, electronic record was the most up to date record.
6. Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). For example, there is no documented training for the following employees: _____ and _____. Also, there is no documentation of training for _____ in the handling of customer complaints.

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information as 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.

We received a response from K.A. Rasmussen dated March 31, 2004, concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is inadequate because the response is not in English.

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.

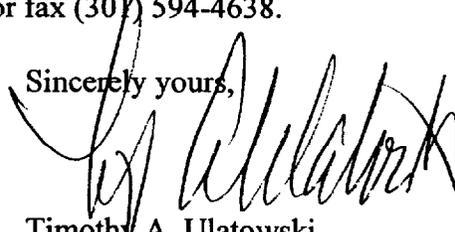
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, which may include refusing entry of your dental endosseous implants and attachments under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated, until the violations are corrected.

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, and Ophthalmic Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Keisha Thomas.

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

Sincerely yours,



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