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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 1998

WARNING LETTER
VIA FEDERAL EXPRESS

Ms. Barbara Vollrath
Managing Director
Oraltronic Vertriebs GmbH
Herrlichkeit 4
D-28199 Bremen, Germany

Dear Ms. Vollrath:

During an inspection of your facility located in Bremen, Germany, on September 17-23, 1998, our investigator determined that your firm manufactures endosseous implants. These endosseous implants are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The current inspection disclosed that your firm has corrected all but one of the previously cited observations, but continues to deviate significantly from the QSR/GMP regulation as indicated by the deviations delineated below.

The above-stated 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 Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to validate a process, where the results of the process cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example, the process for packaging the product in the packages labeled as sterile, wherein product integrity is not compromise, has not been validated.
2. Failure to implement procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 820.80(d). For example, post-sterilization package integrity testing, visual or otherwise, has not been performed.
3. Failure to establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, pending the use or distribution of products, as required by 21 CFR 820.150(a). For example,

the failure to establish procedures to ensure product, which has been labeled as sterile, but has not yet been sterilized, is properly labeled as to its non-sterile status while in storage/shipment prior to sterilization.

4. Failure to maintain a device history records to include the primary identification label and labeling used for each production unit, as required by 21 CFR 820.184(e). For example, the device history records for Osteoplate 2000 blade implants, [REDACTED] do not include records of specific label and labeling used for each production run, nor do other device history records contain specific labels and labeling used for production runs.
5. Failure to base sampling plans on a valid statistical rationale, as required by 21 CFR 820.250(b). For example, current sampling plans described in Working Instruction, "Random Sampling and Testing Plan" [REDACTED] dated 9/16/98 is not based on a valid statistical rationale.
6. Failure to establish and maintain adequate procedures for quality audits, as required by 21 CFR 820.22. For example, neither [REDACTED] "Internal Quality Audits," nor any other procedure, specified the frequency with which audits must be conducted.

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 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 Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Therefore, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information in to account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

Given the serious nature of these violations of the Act, all devices manufactured by Oraltronic, located in Bremen, Germany may be detained upon entry into U.S. until these violations are corrected.

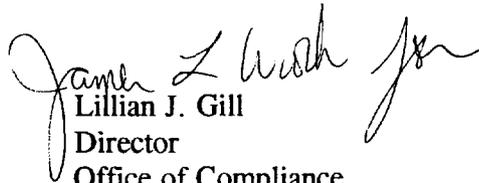
In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your

facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified your products may resume entry into this country.

Please notify this office in writing within 15 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 system problems necessary to assure that similar violations will not recur. Any and all documentation showing plans for correction should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the attention of Mr. Ronald L. Swann, Dental, ENT, and Ophthalmic Devices Branch, at the letterhead address.

Sincerely yours,


Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health