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NOV 30 2001

WARNING LETTER
VIA FEDERAL EXPRESSFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

Mr. Kyoo-Ok Choi
President
OSSTEM Implant Co., Ltd.
38-44, Guje 3-Dong, Yonje-Ku
Busan, Korea

Dear Mr. Choi:

During the Food and Drug Administration's (FDA) September 3 - 6, 2001, inspection of your firm, OSSTEM Implant Co., Ltd., located at 38-44, Guje 3-Dong, Yonje-Ku, Busan, Korea, our investigator determined that your firm manufactures the 3A Dental Implant System. This product is a device within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-mentioned inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packaging, storage, or installation are not in conformance with the Quality System Regulations, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

- 1) Failure to validate a process with a high degree of assurance 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:
 - a) Your firm's sterilization validation process is based on the ISO/TR 13409 - Sterilization health care products - Radiation sterilization - Substantiation of 25 kGy as a sterilization dose for small or infrequent production batches. The product unit limit is defined in the Technical Report as quantities of less than 1,000 product units and infrequent as less than once every three months. The investigator reviewed some of your firm's sterilization batches and found that your firm sterilized several batches that contained more than 1,000 product units, and that several batches were all sterilized within a three month period. This exceeds the product unit limit set in the standard. Your firm must revalidate the sterilization process using an applicable standard for your workload.
- 2) Failure to establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR §820.70(e). For example:

- a) Although your firm periodically monitors the clean room, there is no established procedure for periodic clean room testing and monitoring requirements (i.e., air particulate limits).

The inspection also revealed that your device is misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to furnish any material or information to the Food and Drug Administration as required by the Medical Device Reporting (MDR) regulation of 21 CFR, Parts 803 and 804. The inspection revealed the following violations of 21 CFR §803 of the MDR Regulation:

- 1) Failure to develop, maintain, and implement MDR procedures as required by 21 CFR §803.17. Specifically, you have not established MDR procedures to ensure compliance with any of the requirements of MDR, Parts 803 or 804 which includes a standardized review process for identification, communication, and evaluation of events which meets the criteria for reporting.
- 2) Failure to establish and maintain MDR event files, as required by 21 CFR §803.18. You do not have an MDR file, which is prominently identified as such, where MDR reportable events are maintained.

MDR Regulation information can be accessed via FDA's website at www.fda.gov.

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 FDA 483 issued at the close 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 FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. 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.

You should take prompt action to correct these and any other manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may result in the detention of your device(s) without physical examination upon entry into the United States.

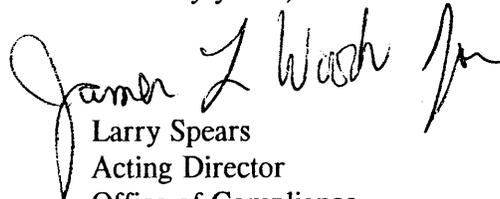
Please notify this office, in writing, within 15 working days of receipt of this letter, the specific steps you have taken to correct the noted violations. Please include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not occur. Please include any and all

Page 3 - Mr. Kyoo-Ok Choi

documentation to show that adequate correction has been achieved. In the case of future corrections, please provide an estimated date of completion, and documentation showing plans for correction with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review.

Please address your response to Mr. Ronald L. Swann, Chief, Dental, ENT, and Ophthalmic Devices Branch, at the letterhead address. Should you have any questions regarding this letter, please contact Mr. Ernest N. Smith at the letterhead address or by telephone at (301) 594-4613 or FAX at (301) 594-4638.

Sincerely yours,

A handwritten signature in black ink that reads "Larry Spears". The signature is written in a cursive style with a large initial "L" and a stylized "S".

Larry Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health