Implant Dental Technology Co., Ltd. 10/25/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER
OCT 25, 2016

VIA UNITED PARCEL SERVICE

Lang Wu
President/General Manager
Implant Dental Technology Co., Ltd.
No. 5 Shui Bian Ind. Zone
Heng Li Town, Dongguan,
523470 Guangdong
China

Dear Lang Wu:

During an inspection of your firm located in Guangdong, China on June 27, 2016, through June 30, 2016, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures: porcelain-fused-to-metal restorations, porcelain restorations, partial dentures and full dentures. Under section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321 (h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or

prevention of disease, or to affect the structure or function of the body.

This inspection revealed that these devices are 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 requirements of the Quality System regulation found at Title 21 , Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to, the following:

1. 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, four **(b)(4)** Steam Cleaners, located in **(b)(4)** clean rooms and used throughout the manufacturing process to steam clean dental implants, have unidentified green/brown particulate accumulation within the water tanks. Also, your firm stated **(b)(4)** is used for this process instead of **(b)(4)** water.

2. Failure to develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a).

For example, your firm's **(b)(4)** procedures lack instructions for using furnaces to **(b)(4)** metals and to process various porcelains for dental implants. In addition, your firm does not document times and temperatures for these processes.

3. 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, **(b)(4)** used to measure the wall thickness of ceramic teeth lack identification indicating calibration status, as required by your firm's Calibration Procedure, **(b)(4)**, sections 6.44 and 6.5

4. Failure to identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria, as required by 21 CFR 820.86.

For example, your firm's Unqualified Produce Procedure, **(b)(4)**, Rev. A 1, is lacking in that products going through incoming inspection lack identification of acceptance status for temporary storage or for use during manufacturing.

5. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA) to include requirements for analyzing sources of quality data to identify existing and potential causes of nonconforming product, or other

quality problems, as required by 21 CFR 820.100(a)(1).

For example, your firm has not evaluated sources of quality data to identify the need for conducting CAPAs for several time periods during 2013, 2014 and 2015. Your firm does not enter all sources of quality data such as in-process and supplier nonconformances into the CAPA system.

6. Failure to establish and maintain procedures to control all documents, as required by 21 CFR 820.40.

For example, your firm's procedures lack approval signatures and dates. In addition, your firm does not maintain records of changes to include description of the changes, identification of the affected documents, the signatures of the approving individuals, the approval dates, and when the changes become effective.

Our inspection (also) revealed that your firm's porcelain-fused-to-metal restorations, porcelain restorations, partial dentures and full dentures devices are misbranded under section 502(t) (2) of the Act, 21 U.S.C. § 352(t) (2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 -Medical Device Reporting. Significant violations include, but are not limited to, the following:

Failures to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17.

For example, the investigator collected an example of a complaint and the complaint did not contain reference to MDR review. Also, your firm's Customer Satisfaction Control Procedure, IDTQP-012, Rev. A 1, contains no reference to MDR review.

Given the serious nature of the violations of the Act, porcelain-fused-to-metal restorations, porcelain restorations, partial dentures and full dentures manufactured by your firm are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violation(s) described in this letter. We will notify you regarding the adequacy of your firm's response(s) and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Also, U.S. federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices

to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 3540, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #506873 when replying.

If you have any questions about the contents of this letter, please contact: Daniel Walter at feb@fda.hhs.gov (email) or +1-240-402-4020 (telephone).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health

cc: Sam Gaetano-CDT
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U.S. Food and Drug Administration
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