# Denttio, Inc. 2/23/17

U.S. FOOD & DRUG ADMINISTRATION

Los Angeles District
19701 Fairchild Road
Los Angeles, CA 92612

**VIA UNITED PARCEL SERVICE**
**SIGNATURE REQUIRED**

**WARNING LETTER**

February 23, 2017

**WL# 16-17**

Mr. Young Han, President
Denttio, Inc.
3235 N. San Fernando Rd. Bldg. 7B
Los Angeles, CA 90065-1434

Dear Mr. Han:

During an inspection of your firm located in Los Angeles, California, conducted from August 16-19, 2016, an investigator from the United States Food and Drug Administration (FDA) determined that your firm operates as a manufacturer of digital x-ray image receptors and intraoral microscope/cameras. 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 any 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.

We received a response from you dated August 30, 2016, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, which was issued to your firm on August 19, 2016. Our review of the response found that you stated you were missing formal SOPs and Documentation. You stated that you would call for a Management Review Meeting in August 2016. You also provided a "Completion Schedule Plan". However, we consider the response non-substantive as you did not provide detail or documented evidence to address the violations found during the inspection.

Noted violations include, but are not limited to, the following:

1. Failure to establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit as required by 21 CFR 820.198(a). For example, nineteen out of nineteen complaint records reviewed for your firm's Digital X-Ray Sensors to take x-rays were not evaluated for Medical Device Reporting (MDR) and did not include an investigation, or justification for no investigation conducted.

2. Failure to establish procedures for corrective and preventive action as required by 21 CFR 820.100(a). For example, three out of three CAPA records reviewed failed to document an investigation. Two out of two CAPA records were reported as Closed but failed to include verification or validation of the corrective actions.

3. Failure to establish a design history file as required by 21 CFR 820.30(j). For example, your firm has not established a Design History File (DHF) for the Tio-H Digital X-Ray Sensor System.

4. Failure to perform device software validation and risk analysis as required by 21 CFR 820.30(g). For example, you do not have records to demonstrate that your Imaging Software used with the Tio-H Digital X-Ray Sensor has been validated. You do not have records to demonstrate that your firm has conducted a risk analysis to identify potential hazards and control measures with the Tio-H Digital X-Ray Sensor System.

5. Failure to maintain device master records as required by 21 CFR 820.181. For example, your firm has not implemented a Device Master Record for the Tio-H Digital X-Ray Sensor System.

6. Failure to establish procedures for finished device and incoming product acceptance as required by 21 CFR 820.80. Eleven out of eleven Device History Records [DHR] reviewed failed to include documentation of final acceptance activities; review of the data and documentation; release authorization signature; and dated authorization. In addition, incoming sensors undergo some tests but there are no procedures that define how the tests are performed.

7. Failure to establish Device History Record procedures as required by 21 CFR 820.184. For example, eleven out of eleven DHRs lacked the primary identification label and labeling used for each production unit.

8. Failure to adequately establish procedures to ensure equipment is routinely calibrated, inspected, checked, and maintained as required by 21 CFR 820.72(a). For example, your firm utilizes an **(b)(4)** for functional testing of your Digital X-Ray Sensors. However, you have not established procedures with specific directions and limits for accuracy and precision.

9. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system as required by 21 CFR 820.20(c). For example, your Management Review procedure requires a yearly review, in March. However, you did not conduct review meetings in 2015 or 2016. Since the facility was established in 2011, only one management meeting occurred, in 2014.

10. Failure to perform quality audits as required by 21 CFR 820.22. For example, your Internal Quality Audits procedure requires quality audits yearly per the Internal Audit Plan for each quality system. However, you Audit Plans

were not established for 2015 and 2016 and quality audits were not conducted since the establishment of the firm in 2011.

11. Failure to adequately establish procedures for training and identify training needs as required by 21 CFR 820.25(b). For example, your **(b)(4)** requires that training needs be identified and that employees possess the required knowledge and skills for performing their jobs. You do not have records to demonstrate that training needs have been identified and that training has been conducted.

12. Failure to establish document control procedures as required by 21 CFR 820.40 (a). For example, thirty out of thirty procedures provided during the inspection have not been reviewed and approved.

Our inspection also revealed that these 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 regarding the devices 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:

1. Failure to establish MDR procedures as required by 21 CFR 803.17. For example, your firm has failed to develop, maintain and implement written Medical Device Reporting (MDR) procedures.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure compliance with all requirements of federal law and FDA regulations. You should take prompt action to correct the violations cited in this letter.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations and copies of supporting documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the date by which you will have completed the correction.

Your response should be sent to:

Kelly D. Sheppard, Director
Compliance Branch
Food and Drug Administration
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612

If you have any questions about the content of this letter, please free to contact Dr. Raymond W. Brullo, Compliance Officer, at 949-608-2918 or **raymond.brullo@fda.hhs.gov. (mailto:raymond.brullo@fda.hhs.gov)**

Sincerely,
/S/
CDR Steven E. Porter, Jr.
Los Angeles District Director

cc: