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September 26, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-52-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John C. Miles
Chairman & CEO
Dentsply International Inc.
570 W. College Ave.
York, PA 17405

Dear Mr. Miles:

During an inspection of your firm's Professional Division (located at 901 W. Oakton St., Des Plaines, IL) from March 5 to March 15, 2001, Investigator Tamara Brey determined that your establishment manufactures dental handpieces and dental accessories. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The 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 Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures for corrective and preventive action that include requirements for:
 - 1.1. Analyzing service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other sources of quality problems.
 - 1.2. Verifying or validating corrective or preventive actions to ensure that such action is effective and does not adversely affect the finished device.
2. Failure to document corrective and preventive action activities and their results. For example, seven of eight product/quality problems discussed during the February 2001 Product Surveillance Committee meeting were not linked to or associated with the Corrective Action Notification System Action Log and System.

3. Failure to complete the investigation of complaints that involve the failure of a device. For example, Complaint No. RA0914-073 was closed without completing the investigation of out-of-tolerance components and a stress line inside the chuck and without review of the Device History Record.
4. Failure to maintain a Device Master Record for the Quiet Air High Speed Dental Handpiece that contains or makes reference to all device specifications, production process specifications, quality assurance procedures, packaging and labeling specifications, and service procedures.
5. Failure to maintain Device History Records for Turbine Cartridges (Part Numbers 790118, 780118, 750118, 484300, 464300, and 464299 sold as a replacement part.) that include, or refer to, the location of acceptance records that demonstrate the device is manufactured in accordance with the Device Master Record.
6. Failure to maintain procedures for inspection of incoming product. For example, your firm did not perform annual and quarterly microbiological testing of handpiece lubricants, as required by the "Resale Liquids Control," Doc. No. MW15P04, Rev. B, dated 9/5/97, for at least three years.
7. Failure to identify the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. For example, areas used to segregate nonconforming material or scrap in the Quiet Air Cell manufacturing floor were not identified as "quarantine," "nonconforming," or "rejected."
8. Failure to establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. For example, your firm had no rework procedures for nonconforming product produced in the Quiet Air Cell Manufacturing Area.
9. Failure to maintain procedures to ensure that the device design is correctly translated into production specifications. For example, the [REDACTED] Syringe software source code version 1.6 did not go through a formally documented design transfer process. The source code's electronic file transfer to the master chip before production release was not documented and the approved source code version 1.6 (hardcopy or electronic file) was not retained under Document Controls.
10. Failure to confirm that device output meets the design input requirements. For example, the results of design verification activity, "LT 1526 Volume of anesthetic dispensed from different brands of cartridge by [REDACTED] Syringe," was accepted even though your firm did not:

- Perform testing with the [REDACTED] cartridges as required in the test protocol.
- Justify accepting the verification activity results without testing with the [REDACTED] cartridges.

We acknowledge receipt of your firm's responses dated April 4, April 9, April 30, and May 31, 2001, from Mr. Hans J. Eppinger, Director, Quality Assurance and Regulatory Affairs, to our FDA-483, dated March 15, 2001. We have reviewed your responses and find that they are inadequate for the following reasons:

We are concerned that your corrective action to Observation 6 lacks retraining of personnel in charge of complaint handling and failure investigation. It appears your response may not address the root cause of the observation. If you decided retraining is not necessary, please justify your reason.

We could not determine if your corrective action for Observation 11 is to test the performance of Turbine Cartridges when manufactured and sold as replacement parts. If you intend to perform and document performance testing of Turbine Cartridges, when manufactured and sold for replacement parts, please submit the test procedures and an example of a Device History Record. If you do not intend to perform and document performance of Turbine Cartridges, when manufactured and sold as replacement parts, please provide justification.

In your response to Observation 13, you did not include the "Final Test Parameter Sheet MWF030" for the Quiet Air L High Speed Handpiece. Therefore, we could not determine if you intend to test for all performance characteristics as described in "ES 6078 Quite-Air Wrenchless Autochuck Test Specification" including chuck pullout force (6 lb. minimum as per section 2.10).

Regarding your response to Observation 16, we disagree with your decision that no rework procedures are required in the Quiet Air Cell. 21 CFR Section 820.90(b)(2), "Nonconforming product, Nonconformity review and disposition," specifically requires rework procedures that include retesting and reevaluation of the nonconforming product after rework. Your current manufacturing procedures do not address such rework issues as the maximum number of times a product can be reworked, what types of rework are acceptable, and who is responsible for reviewing and releasing reworked product.

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 conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

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. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 30 working 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 systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer, at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director

cc: Mr. Hans J. Eppinger
Director, Quality Assurance and Regulatory Affairs
Dentsply International Professional Division
901 West Oakton Street
Des Plaines, IL 60018-1884