DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	6/14/2017-6/15/2017
	FEI NUMBER 3008936312

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael D. Williams , President

FIRM NAME	STREET ADDRESS
Michael D. Williams, D.D.S., P.A.	10991 SW 42nd Pl
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Davie, FL 33328-2137	Specification Developer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for design control have not been established.

Specifically,

a) you do not have design control procedures that define and include requirements for the following:

- Design plans that describe or reference the design and development activities and define responsibility for implementation.
- Design inputs to establish that design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient including a mechanism for addressing incomplete, ambiguous, or conflicting requirements.
- Design outputs for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements, to contain or make reference to acceptance criteria, and ensure that those design outputs that are essential for the proper functioning of the device are identified.
- Design reviews to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development and ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed.

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- Design verification to confirm that the design output meets the design input requirements.
- Design validation of the device to be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents under actual or simulated use conditions to ensure that devices conform to defined user needs and intended uses and also include a risk analysis, where appropriate.
- Design Transfer to ensure that the device design is correctly translated into production specifications.
- Design changes to ensure design changes are identified, documented, validated or where appropriate verified, reviewed, and approved before their implementation. Your device history file procedure titled "Design History Files", Doc. # WI-42-04-1, Rev. A, dated 06/14/2017, Section 6, refers to a design change procedure WI-73-07 "Control of Design and Process Changes" to control the design changes; however, you do not have this procedure.

b) you have not implemented your design history file procedure titled "Design History Files", Doc. # WI-42-04-1, Rev. A, dated 06/14/2017, in that your design history file for the Sleep Tight Mouthpiece does not include the following:

- design plans that describe or reference the design and development activities and define responsibility for implementation;
- inputs that are complete and unambiguous;
- design outputs;
- verification tests including protocols and test reports; and
- validation test(s) including protocols and test report(s) on initial production units under actual conditions of use or simulated environment.

c) you do not have documented evidence of a validation and/or verification performed before implementing a design change to increase the softening point of the mouthpiece fitting handle which you documented on an Engineering Change Request (ECR), form #QF-73-01-2, ECR No. 0001 on 04/09/2015.

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d) you performed a label design change of the Sleep Tight Mouthpiece Insert (undated and no identification number on the Insert labeling) on 05/16/2016 to include amount of water users need to boil and the temperature of the water needed. This design change was not documented, reviewed, approved and you do not have documented evidence of a validation and/or verification performed for this change before implementing this design change.

OBSERVATION 2
Complaint files are not adequately maintained.

Specifically,

a) you have not implemented your procedure for complaint handling titled "Customer Complaints", Doc. #QOP-85-03, Rev. A, effective date 06/01/2014, in that your complaint records do not have:

- The name of the device;
- The date the complaint was received;
- Any device identification(s) and control number(s) used;
- The address and phone number of the complainant;
- The dates of the investigation; or
- Reference to any corrective or preventive action taken;

b) A total of 632 complaint records of the 1,089 received from November 2014 – June 2017 do not have the nature and details of the complaint.

c) you have not documented evaluations for MDR events for any of your complaints. As an example, Complaint RMA #B72MX6, shows the customer indicated as a reason for returning the device as "allergic reaction". There is no documentation to support why you did not consider this event to not be a reportable event and you did not contact the customer to determine the extent of the allergic reaction to determine if it met the definition of a medical device reportable event.

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Written MDR procedures have not been developed.

Specifically, you do not have a Medical Device Reporting (MDR) procedure to ensure that complaints that allegedly results in a death or serious injury are reported to the FDA in accordance with the MDR regulation and to address the documentation and recordkeeping requirements of MDR files. The uncontrolled document you provided is a copy of the regulation which does not provide an internal system for a standardize review process, documentation of information evaluated to determine if an event is a medical device reportable event, and electronic transmission of MDR reports to FDA.

OBSERVATION 4
Procedures for quality audits have not been established.

Specifically, you do not have a quality audit procedure and have not conducted quality audits at your firm.

OBSERVATION 5
Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established.

Specifically,

a) you do not have purchasing control procedures for the documentation and evaluation requirement, including quality requirements, that must be met by your suppliers to ensure that all purchased or otherwise received product and services conform to specified requirements.

b) you do not have records of the evaluation of your label printing and packaging suppliers.

c) you do not have a supplier quality agreement with your contract manufacturer to notify you of changes in the products or services provided to you so that you can determine whether the changes may affect the quality of a finished device.

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d) you do not have evidence to support that you verified that your contract manufacturer has validated their injection molding process used to manufacture your finished device.

OBSERVATION 6
Sampling plans are not based on valid statistical rationale.

Specifically, you perform a fit test of one finished device mouthpiece received from your contract manufacturer. From 2016 - 2017, you have received (b) (4) shipments of five different lots #082934A-F17, #082933A-A16, #0829348-F17, #082933A-A16, and #082932A-O15, ranging in size of (b) (4) from your contract manufacturer. This sample number of one device is not based on a statistical rationale. In addition, you do not know if your contract manufacturer is performing any type of functionality tests or inspections on a number of samples of your finished devices to determine if the finished devices they manufactured for you using an injection molding machine conforms to your specifications.

OBSERVATION 7
Procedures to control labeling activities have not been established.

Specifically, you do not have written procedures to control labeling activities including labeling inspections, labeling storage, and labeling operations and you do not document the labeling inspections and release you perform upon receipt of a new batch of labels received from your label printing supplier.

OBSERVATION 8
Production processes were not developed to ensure that a device conforms to its specifications.

Specifically, you do not have written procedures for the re-packaging operation and you do not document the re-packaging activities of your finished devices performed at your facility.

OBSERVATION 9
Document control procedures have not been established and maintained.

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Specifically,

a) you do not have written procedures to control that provides instructions for document approval, document changes, and maintenance of approved or changed procedures for all documents required by the quality system regulation.

b) the procedure provided for incoming acceptance of finished devices “Batch Inspection Protocol” does not have signatures of the individual(s) approving this document and an effective date. The procedures provided for corrective and preventive action “Corrective and Preventive Action”, Doc. #QOP-85-04, Rev. A, dated 06/01/2014, and complaint handling titled “Customer Complaints”, Doc. #QOP-85-03, Rev. A, dated 06/01/2014, do not have signatures of the individual(s) approving this document. In addition, the first copy of these complaint handling and corrective action procedures provided for my review did not have a signature and indicated a different effective date of 06/21/2013.

OBSERVATION 10
Procedures for corrective and preventive action have not been established.

Specifically, your corrective and preventive action procedure titled "Corrective and Preventive Action Program", Doc. # QOP-85-04, Rev. A, dated 06/01/2014, is not adequate in that it does not include the following requirements:

- Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems using statistical methodology where necessary to detect recurring quality problems;
- Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
- Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

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Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct
Observation 4: Promised to correct
Observation 5: Promised to correct
Observation 6: Promised to correct
Observation 7: Promised to correct
Observation 8: Promised to correct
Observation 9: Promised to correct
Observation 10: Promised to correct

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