DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	4/16/2019-8/23/2019* FEI NUMBER 1039621

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael A. Muscari, Vice President/Co-owner

FIRM NAME	STREET ADDRESS
Health Science Products Inc	1489 Hueytown Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hueytown, AL 35023-2061	Medical Device Manufacturer

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

Written MDR procedures have not been developed, maintained and implemented.

Specifically, you failed to develop and implement written MDR procedures as the manufacturer of medical devices.

OBSERVATION 2

Procedures for corrective and preventive action have not been established.

Specifically, you failed to establish CAPA procedures that include, analysis of sources of quality data, investigations of causes of nonconformities, identification of the actions needed to prevent the recurrence of nonconforming product, verification and/or validation of corrective actions, and implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

OBSERVATION 3

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically, you have not established written complaint handling procedures and do not maintain complaint files.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Wendy R Blame, Investigator	X Wendy R Blame Investigator Signed By: 1300181464 Date Signed: 08-23-2019 12:04:04	8/23/2019

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OBSERVATION 4

A device master record has not been maintained.

Specifically, you failed to establish and maintain device master records for your dental operative units and chairs that includes or refers to the location of all device, quality, production and process, packaging, labeling, and installation specifications.

OBSERVATION 5

A device history record has not been adequately maintained.

Specifically, you failed to maintain production history for each dental operative unit and chair that includes or refers to the location of all acceptance records, the primary identification label or labeling, and any device identification and control numbers used.

OBSERVATION 6

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

Specifically, you purchase the components used to manufacture your dental operative units from suppliers. You failed to establish written purchasing controls to ensure that all received product conforms to specified requirements and that components are not changed without your approval.

OBSERVATION 7

Procedures for quality audits have not been established.

Specifically, you failed to implement procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

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OBSERVATION 8

Management with executive responsibility has not reviewed the suitability and effectiveness of the quality system.

Specifically, you failed to implement management review procedures to review the suitability and effectiveness of the quality system at defined intervals.

*DATES OF INSPECTION

4/16/2019(Tue), 8/21/2019(Wed), 8/23/2019(Fri)

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Annotations to Observations

Observation 1: Under consideration

Observation 2: Under consideration

Observation 3: Under consideration

Observation 4: Under consideration

Observation 5: Under consideration

Observation 6: Under consideration

Observation 7: Under consideration

Observation 8: Under consideration

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."