

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 10/1/2024-10/3/2024
	FEI NUMBER 2082148

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott Veis, Chief Operation Officer

FIRM NAME Space Maintainers Lab	STREET ADDRESS 9129 Lurline Ave
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CITY, STATE, ZIP CODE, COUNTRY Chatsworth, CA 91311-5922	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer
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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 device history records have not been established.

For example,

-- your site has not established a Device History Record Procedure.

-- the device history records for the anti-snoring and jaw positioning class II medical devices does not include, or refer to the location of (UDI) unique device identifier (records of examination and release of device labeling, including date and signature of the examiner).

OBSERVATION 2

Procedures for training and identifying training needs have not been adequately established.

For example, the firm's designated Management Representative and management with executive responsibility have no documented formal training for Quality System Regulation. (repeat FDA-483 observation)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sarah A Hassas, Investigator	Sarah A Hassas Investigator Signed By: Sarah A. Hassas -S Date Signed: 10-03-2024 11:27:07 X _____	DATE ISSUED 10/3/2024

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Sarah A Hassas, Investigator

Sarah A Hassas
Investigator
Signed By: Sarah A. Hassas -S
Date Signed: 10-03-2024
11:27:07

X

DATE ISSUED

10/3/2024

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."