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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214)253-5200 Fax:(214)253-5314 | 5/26/2026-6/1/2026*<br>FEI NUMBER<br>3005515469 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Richard Liu, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| Dentlight Inc | 1825 Summit Ave Ste 210 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Plano, TX 75074-8196 | TYPE ESTABLISHMENT INSPECTED<br>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.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

You did not submit a required product report distinctly marked "(b) (4) Safety Product Report of (your name)" prior to the introduction of the product into commerce.

Specifically, your firm ~~could not locate and/or provide any records demonstrating submission of the required product report, abbreviated report and annual reports~~ **did not submit the required product report prior to the introduction of the product into commerce or annual reports** for your firm's Class IV (b) (4), or (b) (4) devices.

## OBSERVATION 2

Records of servicing activities carried out by your firm or your supplier were not adequately analyzed to determine if the information is to be handled as a complaint.

Specifically, your firm has not adequately analyzed service records to determine if the information is to be handled as a complaint per your procedure Servicing, QSPR-1802, Rev. E, effective 08/30/2024.

## *DATES OF INSPECTION

5/26/2026(Tue), 5/27/2026(Wed), 5/28/2026(Thu), 5/29/2026(Fri), 6/01/2026(Mon)

AMENDMENT 1

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Katherine M Thames, Investigator<br>X Katherine M Thames Investigator Signed By: KATHERINE M. THAMES -S Date Signed: 06-04-2026 11:15:27 | 6/4/2026 |

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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214)253-5200 Fax:(214)253-5314 | 5/26/2026-6/1/2026*<br>FEI NUMBER<br>3005515469 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Richard Liu, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| Dentlight Inc | 1825 Summit Ave Ste 210 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Plano, TX 75074-8196 | TYPE ESTABLISHMENT INSPECTED<br>Manufacturer |

## Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

AMENDMENT 1

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Katherine M Thames, Investigator | X Katherine M Thames Investigator Signed By: KATHERINE M. THAMES -S Date Signed: 06-04-2026 11:15:27 | 6/4/2026 |

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."