

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404		DATE(S) OF INSPECTION 4/29/2026-5/8/2026* FEI NUMBER 1000126901	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Seth E. Jensen, Research and Development Leader			
FIRM NAME Philips Oral Healthcare, LLC		STREET ADDRESS 22100 Bothell Everett Hwy	
CITY, STATE, ZIP CODE, COUNTRY Bothell, WA 98021-8431		TYPE ESTABLISHMENT INSPECTED 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.			
<i>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.</i>			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Specifically, Your firm failed to adequately identify and submit Medical Device Reports (MDRs) in five out of eleven complaints reviewed. For example: a) Complaint case no. 4964785 related to the Power Toothbrush opened on 07/14/2024 and closed on 01/28/2025. The complaint references the device almost catching on fire while charging and burning the consumer's hand. b) Complaint case no. 5563636 related to the Power Toothbrush opened on 01/02/2025 and closed on 04/02/2025. The complaint references the device charger melting and causing property damage. c) Complaint case no. 6104544 related to the Power Toothbrush opened on 05/27/2025 and remained open during the time of this inspection. The complaint references a battery explosion in the device. d) Complaint case no. 6193583 related to the Battery Toothbrush opened on 06/20/2025 and remained open			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Brian R Hendricks, Investigator Brian R Hendricks Investigator Signed By: BRIAN R. HENDRICKS JR -S Date Signed: 05-08-2026 10:07:48 X _____	
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during the time of this inspection. The complaint references the device exploding and melting. e) Complaint case no. 7142503 related to the Power Toothbrush opened on 03/31/2026 and remained open during the time of this inspection. The complaint references the device overheating and causing a hand burn. These cases were noted to have no adverse event and no problem recurrence with their MDR assessments for initial reporting. Your management representative was unable to provide adequate justification in this regard.			
OBSERVATION 2 One or more processes for risk management in product realization have not been adequately documented. Specifically, Your firm's Failure Mode and Effects Analysis (FMEA) for Usability, Doc No. D000517750, Revision E, did not address the scenario where a firmware defect causes a thermal event during normal intended use, which is the primary firmware hazard pathway identified in your risk management matrix documentation. Revision B and Revision D of your firm's Failure Mode and Effects Analysis for Process, Doc No. D001228908, did not include failure modes that address thermal overheating, battery thermal runaway, fire risk, or heat-related manufacturing defects. When asked why thermal events from firmware defects, in addition to entries for manufacturing defects that could contribute to thermal hazards, were not included in the corresponding FMEAs, your management representative was unable to provide adequate justification in this regard.			
OBSERVATION 3 Design and development verification was not adequately performed in accordance with planned and documented arrangements to ensure that design and development outputs met design and development input requirements. Specifically, Your firm failed to document thermal performance and thermal safety testing for the USB-C to Small Plug design			
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change of the Power Toothbrush, which originated from thermal hazards of the previous charging port. Your firm's Product Verification Report, Doc No. D001397970, Revision A.2, and detailed Verification Testing Report, Doc No. D000550175, Revision AA.4, did not contain test IDs that directly address temperature measurement at the charging interface and thermal performance assessment under fault conditions, or the verification of overcharge protection circuit functionality. When asked about the faults with design inputs for safety, your management representative was unable to provide adequate justification in this regard.			
OBSERVATION 4 Design and development validation was not adequately performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Specifically, Your firm failed to adequately document validation for the USB-C to Small Plug design change of the Power Toothbrush, which originated from thermal hazards of the previous charging port. Your firm's report for Product Validation Results, Doc No. D001401015 (DRC-1807) contained outcomes of validated user requirements for the charging interface to include ease of cable insertion, cable length satisfaction, overall ease of use, and ease of cable removal. However, user behaviors classified as Critical to Safety (CTS) in your firm's FMEA for Usability, Doc No. D000517750, Revision D.2 to include non-compliant wall adapter use, handle use while charging, and cable cleaning were not included in the validation scope. When asked about the exclusion of safety-related scenarios from the validation study, your management representative was unable to provide adequate justification in this regard.			
OBSERVATION 5 The results of supplier monitoring were not adequately provided as an input into the supplier re-evaluation process. Specifically, Your firm failed to adequately evaluate ongoing performance of Company (b) (4) a high risk supplier for the Power			
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Toothbrush and Battery Toothbrush devices. Pages 5-6, section 4.3 of the Manage Supplier Quality procedure, Doc No. 16.2.18, states that "The supplier's ongoing performance is reflected in their assigned quality performance rating. If this assessment shows that suppliers have reached or exceeded a pre-defined performance trigger threshold, those suppliers are identified and their quality performance rating is adjusted." The May 2024 supplier audit report for company (b) (4) resulted in a notice that significant improvement was required due to issues cited. However, their supplier performance rating was in good standing and did not change from January 2024 to September 2024. Since the previous audit in May 2024, your firm has not conducted a subsequent audit or re-evaluation to mitigate the performance risk. When asked about the deficiencies identified, your management representative was unable to provide adequate justification in this regard. OBSERVATION 6 Procedures for timely complaint handling have not been adequately documented. Specifically, Your firm does not adhere to the requirement that each organization shall process complaints in a timely manner for three out of eleven complaints reviewed. Page 7 of your firm's Manage Complaints procedure, Doc No. 16.2.8, Revision 4, and Pages 9-11 of your firm's Manage Complaints procedure, Doc No. 16.2.8, Revision 5, states that "complaints are recorded, reviewed and evaluated in a timely manner" in addition to "the objective of closing complaint records within (b) (4) of receipt." For example: a) Complaint case no. 6104544 related to the Power Toothbrush opened on 05/27/2025. Record closure was advised on 06/17/2025 and the case remained open during the time of this inspection. The complaint references a battery explosion in the device. b) Complaint case no. 6193583 related to the Battery Toothbrush opened on 06/20/2025. A request for record closure was not identified and the case remained open during the time of this inspection. The complaint references the device exploding and melting. c) Complaint case no. 6884613 related to the Power Toothbrush opened on 01/13/2026. A request for record closure was entered on 01/27/2026 and the case remained open during the time of this inspection. The complaint references an electrical shock from the device.							
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> EMPLOYEE(S) SIGNATURE Brian R Hendricks, Investigator </td> <td style="width: 40%; border: none; text-align: center;"> DATE ISSUED 5/8/2026 </td> </tr> <tr> <td style="border: none; vertical-align: bottom;"> Brian R Hendricks Investigator Signed By: BRIAN R. HENDRICKS JR -S Date Signed: 05-08-2026 10:07:48 </td> <td style="border: none; vertical-align: bottom;"></td> </tr> </table>		EMPLOYEE(S) SIGNATURE Brian R Hendricks, Investigator	DATE ISSUED 5/8/2026	Brian R Hendricks Investigator Signed By: BRIAN R. HENDRICKS JR -S Date Signed: 05-08-2026 10:07:48	
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Seth E. Jensen, Research and Development Leader

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Your management representative was unable to provide adequate justification for complaint time lines throughout the referenced complaint processing activities.

***DATES OF INSPECTION**

4/29/2026(Wed), 4/30/2026(Thu), 5/01/2026(Fri), 5/04/2026(Mon), 5/05/2026(Tue), 5/06/2026(Wed), 5/08/2026(Fri)

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Annotations to Observations

Observation 1: Annotation Intentionally Left Blank
Observation 2: Annotation Intentionally Left Blank
Observation 3: Annotation Intentionally Left Blank
Observation 4: Annotation Intentionally Left Blank
Observation 5: Annotation Intentionally Left Blank
Observation 6: Annotation Intentionally Left Blank

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Brian R Hendricks, Investigator

Brian R Hendricks
Investigator
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HENDRICKS JR -S
Date Signed: 05-08-2026
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DATE ISSUED

5/8/2026

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."