DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	3/23/2026-3/27/2026* FEI NUMBER 3030627827

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amy Li, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Concha Inc.	55 E 3rd Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Mateo, CA 94401-4010	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

Systematic reviews of design and development were not performed at suitable stages.

Specifically, your firm failed to adequately document the procedure "Design Control," DOC: SOP-006, Effective Date: 06/12/2023, Rev. 01, section 6.11.1 in that your firm failed to conduct formal design reviews at appropriate stages during the design and development of the Concha Sol Hearing Aids (Model CL-1001). Your CAPA 2026-001 (dated March 18, 2026, page 1) identifies "Design Controls - Design reviews not fully documented; DHF incomplete" and proposes corrective action (page 3) to "Conduct retrospective Design Reviews with independent reviewers" and "Complete the Design History File." However, this proposed corrective action has not been completed at the time of this inspection. Your firm has released multiple software versions (1.0.48, 1.0.57, 1.0.59, 1.1.0, 1.1.2), but no design review records were provided demonstrating that formal reviews with independent reviewers were conducted at appropriate development stages for these releases. According to your Chief Executive Officer, your firm did not perform design reviews during design and development of the Concha Sol Hearing Aids or during subsequent software changes.

The absence of design reviews during development prevented systematic evaluation of design adequacy at critical development stages and eliminated the opportunity for multi-functional input and independent assessment to identify design deficiencies before commercial distribution. Without these reviews,

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potential design defects affecting safety and performance may not be identified before devices reach patients. This affects (b) (4) five software versions (1.0.48, 1.0.57, 1.0.59, 1.1.0, 1.1.2) released between 2024 and December 2025.

OBSERVATION 2

Criteria for the evaluation and selection of suppliers were not based on the supplier's ability to provide product that meets requirements, based on the performance of the supplier, based on the effect of the purchased product on the quality of the device and proportionate to the risk associated with the medical device.

Specifically, your firm failed to implement "Supplier Qualification" procedure, DOC: SOP-016, Rev. 01, Effective Date: 04/19/2024 in that you failed to adequately define the criteria for evaluation and selection of suppliers, and failed to conduct an adequate evaluation, monitoring, and re-evaluation of your contract manufacturer prior to and during commercial distribution. Your firm also failed to perform a required (b) (4) audit for this highest-risk supplier of the Concha Sol Hearing Aids (Model CL-1001).

a. Your firm failed to evaluate your contract manufacturer, which makes the hearing aid hardware, prior to selection and commercial distribution of the Concha Sol Hearing Aids. Your firm entered into a Manufacturing and Supply Agreement with your contract manufacturer on March 22, 2023 (effective April 3, 2023) to serve as the contract manufacturer for (b) (4) Concha Sol Hearing Aid hardware, and commercial distribution of the device began in August 2024. However, no supplier evaluation was conducted prior to selecting the contract manufacturer, executing the manufacturing agreement, initiating product development and production, or commencing commercial distribution to customers. On March 24, 2026, your firm's Chief Executive Officer confirmed that she was responsible for selecting the contract manufacturer supplying your firm with the hearing aid hardware and that only supplier questionnaire was completed prior to this selection.

b. Your firm failed to conduct a required (b) (4) audit of your highest-risk supplier as per your SOP-016 Supplier Qualification procedure section 6.2.2. Your firm's contract manufacturer, which makes the hearing aid hardware including (b) (4) (b) (4) (b) (4) which represents the highest risk category for purchased product. Your firm's SOP-016 Supplier Qualification Procedure, Section 6.1.2 classifies suppliers into (b) (4) tiers and defines (b) (4) as including "any integral component of the device that impacts safety" and specifically "contract manufacturers assembling the device." Your contract manufacturer, which supplies (b) (4) hearing aid hardware, clearly qualifies as a (b) (4) supplier based on your firm's own criteria. Despite this classification, no adequate evaluation and/or (b) (4) supplier audit was conducted before selection in March 2023 or during the subsequent three years of the manufacturing relationship through March 2026.

In addition, your firm relied on your contract manufacturer's ISO 13485:2016 certification without adequate verification or documented decision-making regarding the need for supplier audit. The supplier questionnaire (FM032, completed March 17, 2026) indicates the contract manufacturer holds ISO 13485:2016 certification. However, your firm did not verify this certification existed before selecting the contract manufacturer in March 2023, obtain copies of the ISO certificate, review the scope of certification, assess whether the scope covers products manufactured for Concha, review registrar audit reports, or verify certificate validity. Your SOP-016 Section 6.2.2 states: "Depending on the critical nature of the operation or service that the supplier is performing, suppliers that are ISO registered may not be audited. However, if the operation or service is determined to be of a critical nature, Concha Labs reserves the right to perform an audit at the supplier's site of operation." No documented decision was provided showing whether your contract manufacturer's ISO certification was deemed sufficient, whether the critical nature of your contract manufacturer's role as the (b) (4) contract manufacturer of (b) (4) device hardware was assessed, whether an audit was determined necessary or unnecessary, or the

rationale for any such determination.

Without supplier evaluation and monitoring, your firm cannot ensure your contract manufacturer consistently produces devices meeting safety and performance requirements. This can potentially affect (b) (4) commercially distributed units and current production.

c. Your firm has not adequately established and documented the requirements, including quality requirements, that must be met by suppliers. Specifically, your "Manufacturing and Supply Agreement" with your contract manufacturer, which makes the Concha Sol Hearing Aids, effective April 3, 2023, fails to adequately function as a comprehensive quality agreement. The agreement does not fully define the quality system responsibilities and communication procedures between your firm and your contract manufacturer. For example, the agreement does not establish the process or responsibilities for communicating, investigating, and documenting complaints related to products manufactured by your contract manufacturer. It also lacks clear provisions for how your contract manufacturer should notify your firm of manufacturing nonconformances or process changes that could impact the finished device. This deficiency was previously identified in your firm's internal (b) (4) audit in March 2026 and documented in CAPA 2026-001.

Without a comprehensive quality agreement that clearly defines these critical responsibilities, your firm cannot ensure that quality issues arising during manufacturing will be communicated and addressed in a timely and effective manner. This deficiency compromises your ability to meet your post-market surveillance and complaint handling obligations as the legal manufacturer. Failure to receive and investigate this information could prevent the timely identification of systemic quality issues, hinder your ability to conduct necessary corrective actions or reportable events, and potentially delay the removal of unsafe or ineffective devices from the market.

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OBSERVATION 3

Procedures for timely complaint handling have not been adequately documented.

Specifically, your firm's procedure SOP-029, "Complaint Handling," Rev. 01, Effective Date: 06/18/2024 was not adequately implemented in that your firm did not evaluate all sources of customer feedback, such as customer support inquiries and product returns, to determine if they should be processed as complaints. This deficiency has led to the failure to document, evaluate, and investigate instances of customer feedback that allege deficiencies related to the quality, durability, reliability, safety, or performance of the device. For example, the following instances were documented in your (b) (4) customer support records but were not processed through your complaint handling system:

a. Case #1072, received on October 7, 2025, reported a hearing aid with "extremely low sound output."
b. Case #948, received on June 17, 2025 described the software as "buggy," the interface as "not particularly intuitive," and noted "significant issues with one device connecting and the other fading out or not connecting at all."
c. Case #957, dated June 27, 2025, described issues with hearing aids drop the Bluetooth connection, the sound quality was sound, and the left hearing aid seem to go through batteries faster than the right.

By not evaluating all sources of customer feedback as potential complaints, your firm lacks a systematic process for capturing and analyzing data on device performance and potential malfunctions. This failure to establish and maintain an adequate complaint handling procedure compromises key feedback loops within your quality management system. It prevents post-market data from being used as an input for risk management, for detecting nonconforming products, and for identifying the need for corrective and preventive actions. Without a robust process for identifying and investigating all potential complaints, your firm cannot ensure that all quality problems are promptly identified and addressed. This could delay the detection of systemic device issues, thereby potentially exposing other users to a device that may not perform as intended.

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OBSERVATION 4

Design and development inputs related to product requirements do not adequately include functional, performance, usability, or safety requirements, according to the intended use and applicable regulatory requirements or standards.

Specifically, your firm failed to establish design input requirements for insertion depth safety. No design input requirements, design output specifications, engineering drawings, dimensional constraints, or verification test records were provided demonstrating that insertion depth limits were established to prevent the ear tip from contacting the tympanic membrane or being inserted too deeply into the ear canal. Your Instructions for Use (LBL-001 v05, Pages 16-20) provide user instructions for inserting the hearing aids and warn users not to "force the device in your ear," but no quantitative insertion depth specification or safety margin (e.g., minimum distance from tympanic membrane) is documented in design records. On March 24, 2026, your firm's Chief Executive Officer could not provide dimensional specifications or test records demonstrating that insertion depth safety was addressed in the device design.

Insertion depth is a critical safety parameter for receiver-in-canal hearing aids because excessive insertion can cause tympanic membrane contact, pain, injury, or perforation. The OTC hearing aid regulation specifically requires insertion depth that is designed to reduce the risk of the user inserting the device too deeply into the ear canal, recognizing that self-fitting devices require inherent design safeguards to prevent user injury without professional supervision. Without documented insertion depth requirements, design specifications, or verification testing, your firm cannot demonstrate that the device design adequately protects users from this foreseeable hazard. This gap existed throughout product development and commercial distribution (August 2024-March 2026) during which approximately (b) (4) units were distributed for unsupervised self-fitting. Your risk management file (RPT-008) identifies ear tip disconnection risks (Risks #14, 16) but does not assess excessive insertion depth or tympanic membrane contact, indicating this safety concern was not systematically evaluated, and the absence of

quantitative specifications prevents effective complaint investigation or determination of whether reported ear discomfort relates to insertion depth issues.

OBSERVATION 5

Internal audits have not been conducted at planned intervals to determine whether the QMS conforms to planned and documented arrangements and applicable requirements and is effectively implemented and maintained.

Specifically, your firm failed to document internal audit intervals in your procedure "Internal Audit," DOC: SOP-035, Rev. 01, Effective Date: 04/19/2024. Your firm also failed to conduct internal audits at planned intervals to verify quality system compliance and effectiveness. According to your Chief Executive Officer, no internal audit has been completed prior to the (b) (4) conducted in March 2026. Without internal audits, your firm had no independent verification that quality system processes were followed during product development and commercial distribution (2023-2026).

OBSERVATION 6

Top management did not review the quality management system at documented planned intervals to ensure its continued suitability, adequacy, and effectiveness.

Specifically, your firm failed to implement "Management Review" procedure, DOC: SOP-002, Rev. 01, Effective Date: 06/18/2024, which includes the requirements to conduct management reviews of the quality system at a minimum (b) (4) Despite this documented requirement, no management reviews were conducted during (b) (4) (b) (4) According to your firm's Chief Executive Officer, your firm's first ever management review was conducted on March 20, 2026. Without management reviews, top management could not identify systemic quality issues during product development, commercial launch, and sales (2023-2025).

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*DATES OF INSPECTION

3/23/2026(Mon), 3/24/2026(Tue), 3/26/2026(Thu), 3/27/2026(Fri)

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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

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Nga T Ho, Investigator

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Investigator
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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."