

**K233747 Concha Sol Hearing Aids (CL-1001)**Mar 15, 2024  
114 days to decisionK233747 · Product code: **QUH** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k233747/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Self-fitting Air-conduction Hearing Aid, Over The Counter (QUH)
Date received	Nov 22, 2023
Decision date	Mar 15, 2024
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Concha Labs</b>
Location	San Mateo, CA, US
Contact	Carlos Bullock
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Joseph Burke Consulting, Inc.</b>
Contact	Joseph Burke

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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