

K233569 SeptAlignMar 22, 2024
137 days to decisionK233569 · Product code: **NHB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k233569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ear, Nose And Throat, Synthetic, Absorbable (NHB)
Date received	Nov 6, 2023
Decision date	Mar 22, 2024
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spirair, Inc.
Location	San Jose, CA, US
Contact	Tracey Henry
510(k) history	4 submissions · 4 cleared · 2023-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233569/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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