

**K251790 SeptAlign**Jan 16, 2026  
219 days to decisionK251790 · Product code: **NHB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k251790/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ear, Nose And Throat, Synthetic, Absorbable (NHB)
Date received	Jun 11, 2025
Decision date	Jan 16, 2026
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251790/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026