

**K243655 TurbAlign**Jul 11, 2025  
227 days to decisionK243655 · Product code: **LYA** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k243655/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Splint, Intranasal Septal (LYA)
Date received	Nov 26, 2024
Decision date	Jul 11, 2025
Days to decision	227 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/k243655/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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