

K260620 SeptAlign (SPLN001)

Jul 30, 2026
155 days to decision

K260620 · Product code: **NHB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k260620/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ear, Nose And Throat, Synthetic, Absorbable (NHB)
Date received	Feb 25, 2026
Decision date	Jul 30, 2026
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spirair, Inc.
Location	San Jose, CA, US
Contact	Tracey Henry
510(k) history	5 submissions · 5 cleared · 2023-2026