

K180141 SPIWay Endonasal Access GuideFeb 16, 2018
29 days to decisionK180141 · Product code: **LYA** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k180141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Splint, Intranasal Septal (LYA)
Date received	Jan 18, 2018
Decision date	Feb 16, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spiway, LLC
Location	Laguna Beach, CA, US
Contact	Eugene Chen
510(k) history	4 submissions · 4 cleared · 2014-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180141/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026