

K213153 SPIWay Endonasal Access GuideOct 27, 2021
29 days to decisionK213153 · Product code: **LYA** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k213153/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Splint, Intranasal Septal (LYA)
Date received	Sep 28, 2021
Decision date	Oct 27, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	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

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