

K181696 ChitoZolveNov 30, 2018
156 days to decisionK181696 · Product code: **LYA** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k181696/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Splint, Intranasal Septal (LYA)
Date received	Jun 27, 2018
Decision date	Nov 30, 2018
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus Acmi, Inc.
Location	Westborough, MA, US
Contact	Dolan Mills
Website	https://www.olympusmedical.com
510(k) history	42 submissions · 42 cleared · 2007-2026

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