

K230142 Epi-Stop Nasal Gel/epistaxis packMar 22, 2023
63 days to decisionK230142 · Product code: **LYA** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k230142/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Splint, Intranasal Septal (LYA)
Date received	Jan 18, 2023
Decision date	Mar 22, 2023
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomed Ent, Inc.
Location	San Antonio, TX, US
Contact	Antonius Voermans
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Biomed Elements B.V.
Contact	Marcela Garcia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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