

K240763 FirstFit Surgical KitDec 18, 2024
273 days to decisionK240763 · Product code: **EWL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k240763/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Mar 20, 2024
Decision date	Dec 18, 2024
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Freudenberg Medical, LLC
Location	Jeffersonville, IN, US
Contact	Oliver Krause-Huckelberry
510(k) history	3 submissions · 3 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	O'Connell & Myers, LLC
Contact	Trey Thorsen

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

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