FDA 510(k) Premarket Notification

K223932 SafeAir combi (SFR-combi-US)

CLEARED

Apr 26, 2023
117 days to decision

K223932 · Product code: **GEI** · General Hospital
Source: https://www.510kdatabase.net/k223932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 30, 2022
Decision date	Apr 26, 2023
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lina Medical Aps**
Location	Chapel Hill, NC, US
Contact	Jaroslaw Mrowczynski
510(k) history	16 submissions · 16 cleared · 2006-2024