FDA 510(k) Premarket Notification

K222801 Safety Lancet

CLEARED

Jan 25, 2023
131 days to decision

K222801 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Sep 16, 2022
Decision date	Jan 25, 2023
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sarstedt AG & CO KG**
Location	Nuembrecht, DE
Contact	Jochen Hoffman
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Sarstedt, Inc.**
Contact	Susan Smith

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