FDA 510(k) Premarket Notification

K222224 SurgiLance® Safety Lancet

CLEARED

Sep 22, 2022
59 days to decision

K222224 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222224/

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	Jul 25, 2022
Decision date	Sep 22, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medipurpose Pte. , Ltd.**
Location	Alpharetta, GA, US
Contact	Adeline Yi
510(k) history	5 submissions · 5 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	**Regulatory Resources Group, Inc.**
Contact	Julie Stephens

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