FDA 510(k) Premarket Notification

K230287 SaviSafe Safety Device

CLEARED

Nov 21, 2023
292 days to decision

K230287 · Product code: **MEG** · General Hospital
Source: https://www.510kdatabase.net/k230287/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Feb 2, 2023
Decision date	Nov 21, 2023
Days to decision	292 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Suzhou Savicred Biotechnology Co., Ltd.**
Location	Suzhou, CN
Contact	Jiajun Zhu
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Icas Group**
Contact	Ryan Li

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