FDA 510(k) Premarket Notification

K210864 Safety Pen Needle

CLEARED

Feb 17, 2022
331 days to decision

K210864 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k210864/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 23, 2021
Decision date	Feb 17, 2022
Days to decision	331 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sandstone Medical (Suzhou), Inc.**
Location	Suzhou, CN
Contact	Juanjuan Sun
510(k) history	3 submissions · 3 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Grace Liu

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