FDA 510(k) Premarket Notification

K213535 Sterile Safety Hypodermic Needles for Single Use

CLEARED

May 13, 2022
189 days to decision

K213535 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k213535/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 5, 2021
Decision date	May 13, 2022
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zhejiang Kangkang Medical-Devices Co., Ltd.**
Location	Yuhuan, CN
Contact	Chun Guo
510(k) history	4 submissions · 4 cleared · 2021-2022