FDA 510(k) Premarket Notification

K210232 Sterile Hypodermic Needles for Single Use

CLEARED

Sep 23, 2021
238 days to decision

K210232 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k210232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 28, 2021
Decision date	Sep 23, 2021
Days to decision	238 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