FDA 510(k) Premarket Notification

CLEARED

K223334 Sterile Hypodermic Needles for Single Use

Dec 16, 2022
45 days to decision

K223334 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k223334/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 1, 2022
Decision date	Dec 16, 2022
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zhejiang Kindly Medical Devices Co., Ltd.**
Location	Wenzhou, CN
Contact	Zhang Qian
510(k) history	5 submissions · 5 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	**Shanghai Mind-Link Business Consulting Co., Ltd.**
Contact	Amy Li

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