FDA 510(k) Premarket Notification

K233037 Sterile Hypodermic Needles for Single Use

CLEARED

Dec 12, 2023
78 days to decision

K233037 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k233037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 25, 2023
Decision date	Dec 12, 2023
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zhejiang Kindly Medical Device Co., Ltd.**
Location	Wenzhou City, CN
Contact	Zhang Qian
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Shanghai Mind-Link Business Consulting Co., Ltd.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov