FDA 510(k) Premarket Notification

K230635 Pen Needle

CLEARED

Jun 2, 2023
87 days to decision

K230635 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k230635/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 7, 2023
Decision date	Jun 2, 2023
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jiangsu Caina Medical Co.,Ltd**
Location	Jiangyin, CN
Contact	Camel Zhou
510(k) history	21 submissions · 21 cleared · 2018-2024