FDA 510(k) Premarket Notification

K220603 Disposable Medical Safety Hypodermic Needle

CLEARED

Aug 23, 2022
174 days to decision

K220603 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k220603/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 2, 2022
Decision date	Aug 23, 2022
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hantech Medical Device Co., Ltd.**
Location	Ningbo, CN
Contact	Arnold YANG
510(k) history	5 submissions · 5 cleared · 2022-2023