FDA 510(k) Premarket Notification

CLEARED

K232165 Sterile Safety Hypodermic Needles for Single Use

Feb 1, 2024
195 days to decision

K232165 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k232165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 21, 2023
Decision date	Feb 1, 2024
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sterile Hypodermic Needles for Single Use- Disposable Needles; Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needles

APPLICANT

Company	**Berpu Medical Technology Co., Ltd.**
Location	Wenzhou, CN
Contact	Buxin Yu
510(k) history	9 submissions · 9 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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