FDA 510(k) Premarket Notification

K220890 IO Needle Safety Sheath

CLEARED

Oct 31, 2022
217 days to decision

K220890 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k220890/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 28, 2022
Decision date	Oct 31, 2022
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Actuated Medical, Inc.**
Location	Bellefonte, PA, US
Contact	Douglas R. Dillon
510(k) history	10 submissions · 10 cleared · 2012-2025