

K220890 IO Needle Safety SheathOct 31, 2022
217 days to decisionK220890 · Product code: **FMI** · General HospitalSource: <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

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