FDA 510(k) Premarket Notification

K211634 Hypodermic Needle-Pro EDGE Safety Device

CLEARED

Aug 26, 2021
91 days to decision

K211634 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k211634/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 27, 2021
Decision date	Aug 26, 2021
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Smiths Medical Asd, Inc.**
Location	Rockland, MA, US
Contact	Dominique Neisz
510(k) history	52 submissions · 52 cleared · 2004-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k211634/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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