

K211716 DropSafe Safety Pen NeedlesJan 7, 2022
218 days to decisionK211716 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k211716/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 3, 2021
Decision date	Jan 7, 2022
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Htl Strefa SA
Location	Ozorków, PL
Contact	Justyna Zemigala
510(k) history	1 submissions · 1 cleared · 2022-2022

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