

K212095 SurGuard3 Safety Hypodermic NeedleAug 22, 2022
412 days to decisionK212095 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k212095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 6, 2021
Decision date	Aug 22, 2022
Days to decision	412 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Europe N.V.
Location	Leuven, BE
Contact	L. Decoster
510(k) history	28 submissions · 28 cleared · 1999-2025

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