FDA 510(k) Premarket Notification

K212095 SurGuard3 Safety Hypodermic Needle

CLEARED

Aug 22, 2022
412 days to decision

K212095 · Product code: **FMI** · General Hospital
Source: 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