

K192057 K-Pack II Needle - 27G x 1/2" Extra Thin Wall, K-Pack II Needle - 27G x 1/2" Ultra Thin Wall, K-Pack II Needle - 30G x 1/2" Extra Thin Wall, K-Pack II Needle - 30G x 1/2" Ultra Thin WallOct 11, 2019
71 days to decisionK192057 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k192057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 1, 2019
Decision date	Oct 11, 2019
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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