

K230951 Terumo Injection Filter Needle (NF-3013RBKE05M)Oct 18, 2023
197 days to decisionK230951 · Product code: **QYM** · General Hospital
Source: <https://www.510kdatabase.net/k230951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Needle (QYM)
Date received	Apr 4, 2023
Decision date	Oct 18, 2023
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230951/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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