

**K113422 TERUMO SURGUARD 3 SAFETY NEEDLE TERUMO
SURGUARD 3 HYPODERMIC SYRINGE WITH SAFETY NEEDLE**

Mar 5, 2012
105 days to decision

K113422 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k113422/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 21, 2011
Decision date	Mar 5, 2012
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo (Philippines) Corporation
Location	Binan, Laguna, PH
Contact	SANDI HARTKA
510(k) history	5 submissions · 5 cleared · 2012-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k113422/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 3, 2026