FDA 510(k) Premarket Notification

K031453 TERUMO SURGUARD 2 SAFETY NEEDLE

CLEARED

Jul 8, 2003
62 days to decision

K031453 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k031453/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 7, 2003
Decision date	Jul 8, 2003
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Medical Corp.**
Location	Elkton, MD, US
Contact	BARBARA SMITH
510(k) history	143 submissions · 143 cleared · 1980-2011