FDA 510(k) Premarket Notification

K082511 MEDIGARD BLOOD COLLECTION DEVICE

CLEARED

Jan 16, 2009
140 days to decision

K082511 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k082511/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 29, 2008
Decision date	Jan 16, 2009
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medigard Limited**
Location	Crofton, MD, US
Contact	EJ Smith
510(k) history	1 submissions · 1 cleared · 2009-2009