

**K082511 MEDIGARD BLOOD COLLECTION DEVICE**Jan 16, 2009  
140 days to decisionK082511 · Product code: **FMI** · General HospitalSource: <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	<b>Medigard Limited</b>
Location	Crofton, MD, US
Contact	EJ Smith
510(k) history	1 submissions · 1 cleared · 2009-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082511/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 24, 2026