

**K973012 MDC SAFE STEP SAFETY BLOOD COLLECTION  
NEEDLE SYSTEM**Nov 5, 1997  
84 days to decisionK973012 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k973012/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 13, 1997
Decision date	Nov 5, 1997
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>MDC Research , Ltd.</b>
Location	Lake Forest, CA, US
Contact	JAMES M DONEGAN
510(k) history	3 submissions · 3 cleared · 1996-2003

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973012/> 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 29, 2026