

K121632 COMFORT EZAug 10, 2012
67 days to decisionK121632 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k121632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 4, 2012
Decision date	Aug 10, 2012
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Simple Diagnostics, Inc.
Location	Naples, FL, US
Contact	DANIEL KAMM
510(k) history	3 submissions · 3 cleared · 2012-2012

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