

**K133267 DANA REUSABLE TEST PACK**Feb 11, 2014  
110 days to decisionK133267 · Product code: **FRC** · General Hospital  
Source: <https://www.510kdatabase.net/k133267/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Oct 24, 2013
Decision date	Feb 11, 2014
Days to decision	110 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Dana Products, Inc.</b>
Location	South Barrington, IL, US
Contact	HARRY BALA
510(k) history	9 submissions · 9 cleared · 2002-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133267/> 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 7, 2026