

**K143053 KIMGUARD ONE-STEP Sterilization Wrap**Apr 3, 2015  
162 days to decisionK143053 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k143053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Oct 23, 2014
Decision date	Apr 3, 2015
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kimberly-Clark Health Care</b>
Location	Irvin, CA, US
Contact	MONICA KING
510(k) history	5 submissions · 5 cleared · 2013-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143053/> 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 4, 2026