

**K102864 84E SERIES SINGLE PLY WRAPPER**Jan 14, 2011  
106 days to decisionK102864 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k102864/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Sep 30, 2010
Decision date	Jan 14, 2011
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lac Mac, Ltd.</b>
Location	Austin, TX, US
Contact	JEFFREY O STULL
510(k) history	6 submissions · 6 cleared · 2003-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102864/> 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 20, 2026