

**K192147 Halyard ONE-STEP\* Sterilization Wrap**Oct 10, 2019  
63 days to decisionK192147 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k192147/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Aug 8, 2019
Decision date	Oct 10, 2019
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Owens &amp; Minor (O&amp;M) Halyard, Inc.</b>
Location	Mechanicsville, VA, US
Contact	Steven Dowdley
510(k) history	12 submissions · 12 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192147/> 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 May 25, 2026