

**K181959 HALYARD SMART-FOLD\* Sterilization Wrap (H450, H650)**Mar 22, 2019  
242 days to decisionK181959 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k181959/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Jul 23, 2018
Decision date	Mar 22, 2019
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Owens &amp; Minor Halyard, Inc.</b>
Location	Alpharetta, GA, US
Contact	Shriya Kafle
510(k) history	2 submissions · 2 cleared · 2018-2019

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181959/> 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 28, 2026