

**K253454 HALYARD\* ONE-STEP\* Sterilization Wrap**May 18, 2026  
227 days to decisionK253454 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k253454/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Oct 3, 2025
Decision date	May 18, 2026
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HALYARD* QUICK CHECK* Sterilization Wrap; HALYARD* SEQUENTIAL Sterilization Wrap; HALYARD* SMART-FOLD* Sterilization Wrap

**APPLICANT**

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Company	<b>O&amp;M Halyard, Inc.</b>
Location	Alpharetta, GA, US
Contact	Anureet Singh
510(k) history	24 submissions · 24 cleared · 2019-2026

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