

**K214007 HALYARD ONE-STEP Sterilization Wrap, HALYARD
QUICK CHECK Sterilization Wrap**Jul 27, 2022
217 days to decisionK214007 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k214007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Dec 22, 2021
Decision date	Jul 27, 2022
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Owens & Minor (O&M) Halyard, Inc.
Location	Mechanicsville, VA, US
Contact	Anureet Singh
510(k) history	12 submissions · 12 cleared · 2019-2025

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