

**K234050 HALYARD® ONE-STEP® Sterilization Wrap,
HALYARD® QUICK CHECK® Sterilization Wrap, HALYARD®
SEQUENTIAL Sterilization Wrap and HALYARD® SMART-
FOLD® Sterilization Wrap**Sep 16, 2024
270 days to decisionK234050 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k234050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Dec 21, 2023
Decision date	Sep 16, 2024
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	O&M Halyard, Inc.
Location	Alpharetta, GA, US
Contact	Anureet Singh
510(k) history	23 submissions · 23 cleared · 2019-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234050/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026