

K152564 Gemini Sterilization WrapJul 7, 2016
302 days to decisionK152564 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k152564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Sep 9, 2015
Decision date	Jul 7, 2016
Days to decision	302 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, Inc.
Location	Mchenry, IL, US
Contact	Jennifer Mason
510(k) history	238 submissions · 234 cleared · 1977-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152564/> 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 June 2, 2026