

K161910 Cardinal Health Sterilization WrapApr 20, 2017
282 days to decisionK161910 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k161910/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Jul 12, 2016
Decision date	Apr 20, 2017
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardinal Health200, LLC
Location	Waukegan, IL, US
Contact	MEGAN MIDDGAUGH
510(k) history	26 submissions · 26 cleared · 2011-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161910/> 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 1, 2026