

K123289 DURABLUE STERILIZATION WRAPFeb 28, 2013
129 days to decisionK123289 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k123289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Oct 22, 2012
Decision date	Feb 28, 2013
Days to decision	129 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Cardinal Health-Medical Products and Services
Location	Waukegan, IL, US
Contact	LAVENIA FORD
510(k) history	6 submissions · 6 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123289/> 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 7, 2026