

K110954 ARJORAD STERILE WRAPAug 24, 2012
507 days to decisionK110954 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k110954/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Apr 5, 2011
Decision date	Aug 24, 2012
Days to decision	507 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arjo Wiggins Medical, Inc.
Location	Palm Harbor, FL, US
Contact	JON WARD
510(k) history	3 submissions · 3 cleared · 1993-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110954/> 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 14, 2026