

K851340 BLUE SEAL II STERILIZATION POUCHApr 24, 1985
21 days to decisionK851340 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k851340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Apr 3, 1985
Decision date	Apr 24, 1985
Days to decision	21 days
Third-party review	No

APPLICANT

Company	American Sterilizer Co.
Location	Mchenry, IL, US
Contact	JAMES A SPALLINA
510(k) history	36 submissions · 35 cleared · 1977-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k851340/>, 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 23, 2026