

K802919 ISO-BAC INSTRUMENT WRAPFeb 2, 1981
76 days to decisionK802919 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k802919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Nov 18, 1980
Decision date	Feb 2, 1981
Days to decision	76 days
Third-party review	No

APPLICANT

Company	American Convertors Div., American Pharmaseal
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1980-1984

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802919/> 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 29, 2026