

K921909 STERRAD BI TEST PACKOct 1, 1993
526 days to decisionK921909 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k921909/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Apr 23, 1992
Decision date	Oct 1, 1993
Days to decision	526 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Johnson & Johnson Medical, Inc.
Location	Arlington, TX, US
Contact	WENDT
510(k) history	53 submissions · 50 cleared · 1990-2000

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