

K963841 EZTESTFeb 25, 1997
153 days to decisionK963841 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k963841/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Sep 25, 1996
Decision date	Feb 25, 1997
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sgm Biotech, Inc.
Location	Bozeman, MT, US
Contact	JOHN R GILLIS
510(k) history	4 submissions · 4 cleared · 1994-2010

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