

K093794 SMART-READ EZTEST-STEAM SCBI AND TEST PACKMay 14, 2010
155 days to decisionK093794 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k093794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Dec 10, 2009
Decision date	May 14, 2010
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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