

**K091950 SMART-WELL EZTEST INCUBATOR**Jan 15, 2010  
198 days to decisionK091950 · Product code: **FRC** · General Hospital  
Source: <https://www.510kdatabase.net/k091950/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Jul 1, 2009
Decision date	Jan 15, 2010
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091950/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 21, 2026