

**K844344 GEMCAL ENI REFERENCE SERUM**Jan 3, 1985  
55 days to decisionK844344 · Product code: **JIX** · Chemistry  
Source: <https://www.510kdatabase.net/k844344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Nov 9, 1984
Decision date	Jan 3, 1985
Days to decision	55 days
Third-party review	No

**APPLICANT**

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Company	<b>Biocell Laboratories, Inc.</b>
Location	Walker, MI, US
Contact	FALKOWSKI
510(k) history	6 submissions · 6 cleared · 1983-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k844344/>; 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 30, 2026