

**K013708 REFERENCE CHECK, CATALOG NUMBER-RCN-10**Dec 10, 2001  
32 days to decisionK013708 · Product code: **GIZ** · Hematology  
Source: <https://www.510kdatabase.net/k013708/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Control, Normal (GIZ)
Date received	Nov 8, 2001
Decision date	Dec 10, 2001
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Precision Biologic</b>
Location	Dartmouth, N.S., CA
Contact	STEPHEN L DUFF
510(k) history	10 submissions · 10 cleared · 1999-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013708/> 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 15, 2026