

**K954898 PREDICTA ERYTHROPOIETIN KIT (MODIFICATION)**Feb 5, 1996  
138 days to decisionK954898 · Product code: **GGT** · Hematology  
Source: <https://www.510kdatabase.net/k954898/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Erythropoietin (GGT)
Date received	Sep 20, 1995
Decision date	Feb 5, 1996
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genzyme Corp.</b>
Location	Cambridge, MA, US
Contact	ALODIA M RUIZ
Website	<a href="http://www.genzyme.com">http://www.genzyme.com</a>
510(k) history	27 submissions · 27 cleared · 1991-2006

Genzyme Corp. was an American biotechnology company headquartered in Cambridge, Massachusetts. The company specialized in diagnostic and surgical medical devices across multiple therapeutic areas. Genzyme received FDA 510(k) clearances from total submissions between 1991 and 2006. The company's cleared devices spanned chemistry devices, microbiology diagnostics, and surgical implants including wound closure systems and bioresorbable barriers. This regulatory track record reflects the company's broad portfolio across diagnostic and surgical specialties. Genzyme was acquire...

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