

**K992766 N-GENEIOUS LDL-ST CHOLESTEROL REAGENT, N-GENEIOUS LDL-ST CHOLESTEROL CALIBRATOR, GENZYME LDL CHOLESTEROL CONTROL SET**Oct 18, 1999  
62 days to decisionK992766 · Product code: MRR · Chemistry  
Source: <https://www.510kdatabase.net/k992766/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Aug 17, 1999
Decision date	Oct 18, 1999
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genzyme Corp.</b>
Location	Cambridge, MA, US
Contact	BARBARA PIZZA
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...