

K943150 DIRECT LDL CHOLESTEROL IMMUNOSEPARATION REAGENT KITMar 15, 1995
258 days to decisionK943150 · Product code: MRR · Chemistry
Source: <https://www.510kdatabase.net/k943150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Jun 30, 1994
Decision date	Mar 15, 1995
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Corp.
Location	Cambridge, MA, US
Contact	ALODIA M RUIZ
Website	http://www.genzyme.com
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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