FDA 510(k) Premarket Notification

K911406 HDL CHOLESTEROL REAGENT

CLEARED

May 22, 1991
54 days to decision

K911406 · Product code: **LBR** · Chemistry
Source: https://www.510kdatabase.net/k911406/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Hdl (LBR)
Date received	Mar 29, 1991
Decision date	May 22, 1991
Days to decision	54 days
Third-party review	No

APPLICANT

Company	**Genzyme Corp.**
Location	Cambridge, MA, US
Contact	RUSSELL H HERNDON
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...