FDA 510(k) Premarket Notification

CLEARED

K971190 N-GENEOUS HDL CHOLESTEROL KIT/CHOLESTEROL CALIBRATOR

Jun 16, 1997
77 days to decision

K971190 · Product code: **LBS** · Chemistry
Source: https://www.510kdatabase.net/k971190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Mar 31, 1997
Decision date	Jun 16, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Genzyme Corp.**
Location	Cambridge, MA, US
Contact	Nancy E Isaac
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...