

**K021316 ULTRA N-GENEOUS HDL CHOLESTEROL REAGENT
1/REAGENT2**Jul 25, 2002
91 days to decisionK021316 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k021316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Apr 25, 2002
Decision date	Jul 25, 2002
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary
Other names	ULTRA N-GENEOUS HDL CHOLESTREOL CALIBRATOR

APPLICANT

Company	Genzyme Corp.
Location	Cambridge, MA, US
Contact	BARABRA PIZZA
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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