

K040241 N-GENEIOUS WIDE RANGE CRP REAGENT AND CALIBRATOR SETJun 25, 2004
143 days to decisionK040241 · Product code: **DCK** · Chemistry
Source: <https://www.510kdatabase.net/k040241/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Feb 3, 2004
Decision date	Jun 25, 2004
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Corp.
Location	Cambridge, MA, US
Contact	FRED D LASKY
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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