

K023544 GENZYME CONTRAST II HCG URINE/SERUM TESTJan 16, 2003
86 days to decisionK023544 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k023544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 22, 2002
Decision date	Jan 16, 2003
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Corp.
Location	Cambridge, MA, US
Contact	E.V. GOORCHENKO
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...
