

K963425 GENZYME DIAGNOSTICS CONTRAST MONOFeb 25, 1997
179 days to decisionK963425 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k963425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Aug 30, 1996
Decision date	Feb 25, 1997
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Diagnostics
Location	San Diegi, CA, US
Contact	DELIA R BETHELL, PH.D.
510(k) history	5 submissions · 5 cleared · 1996-2005

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