

**K894975 IMMUNODOT INFECTIOUS MONONUCLEOSIS TEST**Sep 13, 1989  
37 days to decisionK894975 · Product code: **KTN** · Immunology  
Source: <https://www.510kdatabase.net/k894975/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Aug 7, 1989
Decision date	Sep 13, 1989
Days to decision	37 days
Third-party review	No

**APPLICANT**

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Company	<b>General Biometrics, Inc.</b>
Location	San Diego, CA, US
Contact	KIEHL, PHD
510(k) history	23 submissions · 23 cleared · 1989-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894975/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026