

**K012901 COLOR-MONOGEN**Sep 27, 2001  
29 days to decisionK012901 · Product code: **KTN** · Immunology  
Source: <https://www.510kdatabase.net/k012901/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Aug 29, 2001
Decision date	Sep 27, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Instrumentation Laboratory CO</b>
Location	Mchenry, IL, US
Contact	CAROL MARBLE
510(k) history	321 submissions · 320 cleared · 1976-2023

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