

K030215 BIORAPID MONONUCLEOSISFeb 24, 2003
34 days to decisionK030215 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k030215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Jan 21, 2003
Decision date	Feb 24, 2003
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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