

K972457 MONOCOL/LEX-IM TESTDec 1, 1997
153 days to decisionK972457 · Product code: **KTN** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Jul 1, 1997
Decision date	Dec 1, 1997
Days to decision	153 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Immunostics Inc.,
Location	Ocean, NJ, US
Contact	DAVID MYCOCK
510(k) history	14 submissions · 14 cleared · 1997-2023

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