

K972231 OSOM MONO TEST 143Aug 26, 1997
71 days to decisionK972231 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k972231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Jun 16, 1997
Decision date	Aug 26, 1997
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wyntek Diagnostics, Inc.
Location	San Diego, CA, US
Contact	SHU-CHING CHENG
510(k) history	12 submissions · 12 cleared · 1995-2000

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