

K883004 MONO-PLUS(TM)Aug 4, 1988
17 days to decisionK883004 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k883004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Jul 18, 1988
Decision date	Aug 4, 1988
Days to decision	17 days
Third-party review	No

APPLICANT

Company	Wampole Laboratories
Location	Mchenry, IL, US
Contact	ANN MACLEARIE
510(k) history	12 submissions · 12 cleared · 1976-1997

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