

K884007 CARDS(TM) MONONov 18, 1988
58 days to decisionK884007 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k884007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Sep 21, 1988
Decision date	Nov 18, 1988
Days to decision	58 days
Third-party review	No

APPLICANT

Company	Pacific Biotech, Inc.
Location	Mchenry, IL, US
Contact	SHU-CHING CHENG
510(k) history	29 submissions · 29 cleared · 1983-1993

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