

K881247 MONO-PHILEApr 7, 1988
15 days to decisionK881247 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k881247/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Mar 23, 1988
Decision date	Apr 7, 1988
Days to decision	15 days
Third-party review	No

APPLICANT

Company	Bio Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	BERNARD FISHBEIN
510(k) history	2 submissions · 2 cleared · 1982-1988

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