

K961024 BIOSIGN MONO-PLUS WB, BIOSIGN MONO WB, MONO-PLUS WB, ACCUSIGN MONO WBFeb 4, 1997
327 days to decisionK961024 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k961024/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Mar 14, 1996
Decision date	Feb 4, 1997
Days to decision	327 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Princeton BioMeditech Corp.
Location	Monmouth Junction, NJ, US
Contact	JENO KANG, PH.D.
510(k) history	72 submissions · 72 cleared · 1994-2025

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