

K945289 DOA - IMMUNOASSAY CUT-OFF CALIBRATORDec 13, 1994
43 days to decisionK945289 · Product code: **DKB** · Toxicology
Source: <https://www.510kdatabase.net/k945289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Oct 31, 1994
Decision date	Dec 13, 1994
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medi-Tech, Inc.
Location	Mchenry, IL, US
Contact	MICHAEL D BICK
510(k) history	36 submissions · 35 cleared · 1978-1996

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