FDA 510(k) Premarket Notification

K964348 AIA-PACK B12 ASSAY

CLEARED

Jan 13, 1997
74 days to decision

K964348 · Product code: **CDD** · Chemistry
Source: https://www.510kdatabase.net/k964348/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Oct 31, 1996
Decision date	Jan 13, 1997
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Tosoh Medics, Inc.**
Location	Washington, DC, US
Contact	LORI ROBINSON
510(k) history	41 submissions · 41 cleared · 1990-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k964348/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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