

K930810 TANDEM-R OSTASE IMMUNORADIOMETRIC ASSAYJan 11, 1994
328 days to decisionK930810 · Product code: **CIN** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Alkaline Phosphatase Isoenzymes (CIN)
Date received	Feb 17, 1993
Decision date	Jan 11, 1994
Days to decision	328 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hybritech, Inc.
Location	Mchenry, IL, US
Contact	RON BERGESON
510(k) history	63 submissions · 63 cleared · 1981-1997

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