

K955647 VIDAS ESTRADIOL II (E2II) ASSAYFeb 6, 1996
56 days to decisionK955647 · Product code: **CHP** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	Dec 12, 1995
Decision date	Feb 6, 1996
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Vitek, Inc.
Location	Hazelwood, MO, US
Contact	TERRY MCGOVERN
510(k) history	49 submissions · 49 cleared · 1992-1998

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