

**K041349 LUMINESCENT IMMUNOASSAY KIT FOR THE
DETECTION OF ESTRADIOL IN SALIVA AND SERUM**Sep 24, 2004
127 days to decisionK041349 · Product code: **CHP** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	May 20, 2004
Decision date	Sep 24, 2004
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ibl GmbH
Location	East Stroudsburg, PA, US
Contact	Gary Lehnus
510(k) history	6 submissions · 6 cleared · 2003-2005

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