

K911396 SR1 ESTRADIOL ENZYME IMMUNOASSAYMay 28, 1991
60 days to decisionK911396 · Product code: **CHP** · Chemistry
Source: <https://www.510kdatabase.net/k911396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	Mar 29, 1991
Decision date	May 28, 1991
Days to decision	60 days
Third-party review	No

APPLICANT

Company	Serono-Baker Diagnostics, Inc.
Location	Winchester, VA, US
Contact	DAVID B THOMAS
510(k) history	23 submissions · 23 cleared · 1988-1992

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