

K946199 AURAFLEX(R) ESTRADIOLApr 3, 1995
104 days to decisionK946199 · Product code: **CHP** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	Dec 20, 1994
Decision date	Apr 3, 1995
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Organon Teknika Corp.
Location	Mchenry, IL, US
Contact	C D KAFADER II
510(k) history	130 submissions · 129 cleared · 1980-2000

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