

**K954697 CIBA CORNING ACS ESTRADIOL-6 ASSAY**Dec 13, 1995  
62 days to decisionK954697 · Product code: **CHP** · Chemistry  
Source: <https://www.510kdatabase.net/k954697/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	Oct 12, 1995
Decision date	Dec 13, 1995
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ciba Corning Diagnostics Corp.</b>
Location	East Walpole, MA, US
Contact	STEVEN R RAKITIN
510(k) history	125 submissions · 125 cleared · 1986-1996

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954697/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026