

**K070391 ELECSYS PTH TEST SYSTEM**Mar 20, 2007  
39 days to decisionK070391 · Product code: **CEW** · Chemistry  
Source: <https://www.510kdatabase.net/k070391/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Feb 9, 2007
Decision date	Mar 20, 2007
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	KAY TAYLOR
510(k) history	264 submissions · 263 cleared · 1999-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070391/> 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 June 9, 2026