

**K030329 FASTPACK FREE T4 IMMUNOASSAY**Jul 3, 2003  
153 days to decisionK030329 · Product code: **CEC** · Chemistry  
Source: <https://www.510kdatabase.net/k030329/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Jan 31, 2003
Decision date	Jul 3, 2003
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qualigen, Inc.</b>
Location	Carlsbad, CA, US
Contact	DOROTHY DEINZER
510(k) history	15 submissions · 15 cleared · 2000-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030329/> 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 19, 2026