

**K965142 VITROS IMMUNODIAGNOSTICS PRODUCTS FREE T4  
REAGENT PACK (GEM.1015) FREE T4 CALIBRATORS  
(GEM.CO15)**Mar 18, 1997  
85 days to decisionK965142 · Product code: **CEC** · Chemistry  
Source: <https://www.510kdatabase.net/k965142/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Dec 23, 1996
Decision date	Mar 18, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Johnson &amp; Johnson Clinical Diagnostics, Inc.</b>
Location	Rochester, NY, US
Contact	ANN M QUINN
510(k) history	33 submissions · 33 cleared · 1995-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k965142/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 29, 2026