

**K901475 CLINICAL ASSAYS(TM) GAMMACOAT(TM) M [125I] T4**Jun 20, 1990  
85 days to decisionK901475 · Product code: **CDX** · Chemistry  
Source: <https://www.510kdatabase.net/k901475/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Thyroxine (CDX)
Date received	Mar 27, 1990
Decision date	Jun 20, 1990
Days to decision	85 days
Third-party review	No

**APPLICANT**

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Company	<b>Baxter Healthcare Corp</b>
Location	Mchenry, IL, US
Contact	NANCY A HORNBAKER
510(k) history	505 submissions · 496 cleared · 1977-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k901475/>; 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 17, 2026