

**K915704 AMYLASE (KINETIC) REAGENT SET**Jun 28, 1996  
1675 days to decisionK915704 · Product code: **CJD** · Chemistry  
Source: <https://www.510kdatabase.net/k915704/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrosalicylate Reduction, Amylase (CJD)
Date received	Nov 27, 1991
Decision date	Jun 28, 1996
Days to decision	1675 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Tech Intl. Co.</b>
Location	Rochester Hills, MI, US
Contact	CHEN
510(k) history	13 submissions · 13 cleared · 1990-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915704/> 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 July 1, 2026