

**K964721 VITROS IMMUNODIAGNOSTICS PRODUCTS TOTAL T4
REAGENT PACK (GEM.1005) TOTAL T4 CALIBRATORS
(GEM.C005)**Dec 18, 1996
23 days to decisionK964721 · Product code: **KLI** · Chemistry
Source: <https://www.510kdatabase.net/k964721/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Nov 25, 1996
Decision date	Dec 18, 1996
Days to decision	23 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964721/> Data sourced from FDA 510(k) public records (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. - Generated July 1, 2026