

K964310 VITROS IMMUNODIAGNOSTICS PRODUCT - TOTAL T3 REAGENT PACK (GEM .101) AND TOTAL CALIIBRATION (GEM.C010)

Nov 27, 1996
29 days to decision

K964310 · Product code: **CDP** · Chemistry
Source: <https://www.510kdatabase.net/k964310/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Triiodothyronine (CDP)
Date received	Oct 29, 1996
Decision date	Nov 27, 1996
Days to decision	29 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.net

Device record: <https://www.510kdatabase.net/k964310/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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