

K964308 VITROS IMMUNODIAGNOSTICS PRODUCTS T3 UPTAKE REAGENT PACK (GEM.1025) AND T3 UPTAKE CALIBRATORS (GEM.C025)Nov 27, 1996
29 days to decisionK964308 · Product code: **KHQ** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Triiodothyronine Uptake (KHQ)
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

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