

**K950803 ISOLAB'S GALACTOSE-1-PHOSPHATE URIDYL
TRANSFERASE TEST KITS 800, 4000 SAMPLE**

Sep 21, 1995
212 days to decision

K950803 · Product code: **JJT** · Chemistry
Source: <https://www.510kdatabase.net/k950803/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Feb 21, 1995
Decision date	Sep 21, 1995
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Isolab, Inc.
Location	Mchenry, IL, US
Contact	JANET PERKINS
510(k) history	44 submissions · 44 cleared · 1977-1996

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k950803/> 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 June 29, 2026