

K960664 BARBITURATE SERUM TOX EIA ASSAYMay 6, 1996
80 days to decisionK960664 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k960664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Feb 16, 1996
Decision date	May 6, 1996
Days to decision	80 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Reagents, Inc.
Location	Walker, MI, US
Contact	YUG-GENG TSAY, PH.D.
510(k) history	66 submissions · 66 cleared · 1982-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k960664/> 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 28, 2026