

K915180 OPIATE EIA ASSAYJan 22, 1992
68 days to decisionK915180 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k915180/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Nov 15, 1991
Decision date	Jan 22, 1992
Days to decision	68 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915180/> 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