

K935565 OPIATES MICRO-PLATE ASSAYJul 14, 1995
603 days to decisionK935565 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k935565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Nov 18, 1993
Decision date	Jul 14, 1995
Days to decision	603 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Solarcare Technologies Corp,Inc.
Location	Bethlehem, PA, US
Contact	R. SAM NIEDBALA, PH.D.
510(k) history	28 submissions · 28 cleared · 1991-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935565/> 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