

K944372 STC DIAGNOSTIC AUTO-LYTE PROPOXYPHENE EIAFeb 8, 1995
154 days to decisionK944372 · Product code: **JXN** · Toxicology
Source: <https://www.510kdatabase.net/k944372/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Propoxyphene (JXN)
Date received	Sep 7, 1994
Decision date	Feb 8, 1995
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Solarcare, Inc.
Location	Bethlehem, PA, US
Contact	R. SAM NIEDBALA
510(k) history	6 submissions · 6 cleared · 1993-1995

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