

**K954156 STC DIAGNOSTICS AUTO-LYTE URINARY
LEUKOCYTE ESTERASE ASSAY**Jul 22, 1996
321 days to decisionK954156 · Product code: **KQO** · Chemistry
Source: <https://www.510kdatabase.net/k954156/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Urinalysis System (KQO)
Date received	Sep 5, 1995
Decision date	Jul 22, 1996
Days to decision	321 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954156/> 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