

K962435 STC AUTO-LYTE URINARY GLUCOSE ASSAYDec 26, 1996
185 days to decisionK962435 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k962435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Jun 24, 1996
Decision date	Dec 26, 1996
Days to decision	185 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	OraSure Technologies, Inc.
Location	Bethlehem, PA, US
Contact	LISA VAIL
510(k) history	30 submissions · 29 cleared · 1996-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962435/> 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 May 14, 2026