

K982745 AUTO-LYTE BARBITURATES EIANov 18, 1998
104 days to decisionK982745 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k982745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Aug 6, 1998
Decision date	Nov 18, 1998
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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