

**K001976 STC BARBITURATES INTERCEPT MICRO-PLATE EIA,  
MODEL 1108I**Dec 6, 2000  
160 days to decisionK001976 · Product code: **DIS** · Toxicology  
Source: <https://www.510kdatabase.net/k001976/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Jun 29, 2000
Decision date	Dec 6, 2000
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001976/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026