

**K000399 STC PCP INTERCEPT MICRO-PLATE EIA, MODEL  
11541**May 15, 2000  
98 days to decisionK000399 · Product code: **LCM** · Toxicology  
Source: <https://www.510kdatabase.net/k000399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Feb 7, 2000
Decision date	May 15, 2000
Days to decision	98 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 NEIDBALA
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/k000399/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026