

**K973651 STC COCAINE METABOLITE MICRO-PLATE EIA**Jan 2, 1998  
99 days to decisionK973651 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k973651/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Sep 25, 1997
Decision date	Jan 2, 1998
Days to decision	99 days
Third-party review	No
Summary / Statement	Statement

**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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