

**K982061 STC COCAINE METABOLITE MICRO-PLATE EIA  
(ORASURE DEVICE)**Aug 25, 1998  
82 days to decisionK982061 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k982061/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jun 4, 1998
Decision date	Aug 25, 1998
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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