

**K981388 MICRO-STRIP FOR COCAINE METABOLITES**May 29, 1998  
43 days to decisionK981388 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k981388/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Apr 16, 1998
Decision date	May 29, 1998
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Microdiagnostics, Inc.</b>
Location	Laguna Niguel, CA, US
Contact	ROY CHUNG
510(k) history	10 submissions · 10 cleared · 1991-2001

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