

K050321 ONTRAK TESTCARD 9Apr 18, 2005
68 days to decisionK050321 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k050321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Feb 9, 2005
Decision date	Apr 18, 2005
Days to decision	68 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Varian, Inc.
Location	Lake Forest, CA, US
Contact	LORNA GAMBOA
Website	http://www.varianinc.com/
510(k) history	5 submissions · 5 cleared · 2004-2006

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