

K943710 VERDICT COCAINENov 17, 1994
108 days to decisionK943710 · Product code: **DIO** · Chemistry
Source: <https://www.510kdatabase.net/k943710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Aug 1, 1994
Decision date	Nov 17, 1994
Days to decision	108 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Editek, Inc.
Location	Burlington, NC, US
Contact	CAROLE GOLDEN
510(k) history	7 submissions · 7 cleared · 1994-1996

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