

K950369 VISUALINE II COCAINEMar 21, 1995
49 days to decisionK950369 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k950369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jan 31, 1995
Decision date	Mar 21, 1995
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sun Biomedical Laboratories, Inc.
Location	Cherry Hill, NJ, US
Contact	MING SUN
510(k) history	17 submissions · 17 cleared · 1994-2003

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