

K943376 OPERA SYSTEMSep 14, 1994
63 days to decisionK943376 · Product code: **JJC** · Chemistry
Source: <https://www.510kdatabase.net/k943376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry (sequential Multiple, Continuous Flow) Clinical Use (JJC)
Date received	Jul 13, 1994
Decision date	Sep 14, 1994
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Miles, Inc.
Location	Tarrytown, NY, US
Contact	GABRIEL J MURACA, JR.
510(k) history	11 submissions · 11 cleared · 1993-1995

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