

K942443 AURAFLEX SYSTEMSAug 26, 1994
95 days to decisionK942443 · Product code: **JJE** · Chemistry
Source: <https://www.510kdatabase.net/k942443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE)
Date received	May 23, 1994
Decision date	Aug 26, 1994
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Organon Teknika Corp.
Location	Mchenry, IL, US
Contact	C. Donald Kafader II
510(k) history	130 submissions · 129 cleared · 1980-2000

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