

K943787 AURATEK FDPSep 20, 1994
48 days to decisionK943787 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k943787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Aug 3, 1994
Decision date	Sep 20, 1994
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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