

K974776 MDA D-DIMERApr 16, 1998
115 days to decisionK974776 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k974776/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Dec 22, 1997
Decision date	Apr 16, 1998
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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