

K000492 MDA D-DIMERJun 7, 2000
113 days to decisionK000492 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k000492/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Feb 15, 2000
Decision date	Jun 7, 2000
Days to decision	113 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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