

K912876 FIBRINOSTIKA FBDP MICROELISA SYSTEMOct 9, 1991
100 days to decisionK912876 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k912876/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Jul 1, 1991
Decision date	Oct 9, 1991
Days to decision	100 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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