

K915698 FIBRINOSTIKA TDP MICROELISA SYSTEMAug 5, 1992
226 days to decisionK915698 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k915698/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Dec 23, 1991
Decision date	Aug 5, 1992
Days to decision	226 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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