

**K924892 FIBRINOSTIKA(R) FGDP MICROELISA SYSTEM**Apr 21, 1994  
569 days to decisionK924892 · Product code: **DAT** · Hematology  
Source: <https://www.510kdatabase.net/k924892/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Split Products, Peroxidase, Antigen, Antiserum, Control (DAT)
Date received	Sep 29, 1992
Decision date	Apr 21, 1994
Days to decision	569 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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