

K012755 AUTODIMER ASSAY MODEL # 1431Mar 15, 2002
211 days to decisionK012755 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k012755/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Aug 16, 2001
Decision date	Mar 15, 2002
Days to decision	211 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Xtrana, Inc.
Location	Ventura, CA, US
Contact	PATRICK J O'LEARY
510(k) history	1 submissions · 1 cleared · 2002-2002

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