

K002642 MINIQUNT D-DIMER, MODEL 1447Feb 5, 2001
165 days to decisionK002642 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k002642/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Aug 24, 2000
Decision date	Feb 5, 2001
Days to decision	165 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biopool Intl., Inc.
Location	Ventura, CA, US
Contact	MICHAEL D BICK
510(k) history	4 submissions · 4 cleared · 1998-2001

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