

K994341 FIBRINOGEN CALIBRATOR KITMar 3, 2000
71 days to decisionK994341 · Product code: **GFX** · Hematology
Source: <https://www.510kdatabase.net/k994341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen Standard (GFX)
Date received	Dec 23, 1999
Decision date	Mar 3, 2000
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	REBECCA S AYASH
510(k) history	343 submissions · 343 cleared · 1978-2010

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