FDA 510(k) Premarket Notification

K072304 FIBRINOGEN CALIBRATOR KIT

CLEARED

Sep 19, 2007
33 days to decision

K072304 · Product code: **GFX** · Hematology
Source: https://www.510kdatabase.net/k072304/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen Standard (GFX)
Date received	Aug 17, 2007
Decision date	Sep 19, 2007
Days to decision	33 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dade Behring, Inc.**
Location	Newark,, DE, US
Contact	RADAMES RIESGO
510(k) history	343 submissions · 343 cleared · 1978-2010