

K093848 PT-MULTI-CALIBRATOR, MODEL OPAT07Dec 20, 2010
369 days to decisionK093848 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k093848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Dec 16, 2009
Decision date	Dec 20, 2010
Days to decision	369 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

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