

**K002885 DADE PFA-100 PLATELET FUNCTION ANALYZER
MODEL-100, DADE PFA COLLEGEN/EPINEPHRINE TEST
CARTRIDGE, DADE PFA COLLEGEN /ADP**

Jun 21, 2001
279 days to decision

K002885 · Product code: **JOZ** · Hematology
Source: <https://www.510kdatabase.net/k002885/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Automated Platelet Aggregation (JOZ)
Date received	Sep 15, 2000
Decision date	Jun 21, 2001
Days to decision	279 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k002885/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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