

**K060489 DADE PFA-100 PLATELET FUNCTION ANALYZER  
AND REAGENTS**Jul 21, 2006  
147 days to decisionK060489 · Product code: **JOZ** · Hematology  
Source: <https://www.510kdatabase.net/k060489/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Automated Platelet Aggregation (JOZ)
Date received	Feb 24, 2006
Decision date	Jul 21, 2006
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060489/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 19, 2026