

**K970505 DADE PFA-100 PLATELET FUNCTION ANALYZER/PFA
 COLLAGEN/EPINEPHRINE TEST CARTRIDGE/PFA
 COLLAGEN/ADP TEST CARTRIDGE/**

Nov 17, 1997
 280 days to decision

K970505 · Product code: **JOZ** · Hematology
 Source: <https://www.510kdatabase.net/k970505/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Automated Platelet Aggregation (JOZ)
Date received	Feb 10, 1997
Decision date	Nov 17, 1997
Days to decision	280 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Intl., Inc.
Location	Deerfield, IL, US
Contact	BRYAN SCHNEIDER
510(k) history	30 submissions · 30 cleared · 1995-1998

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Device record: <https://www.510kdatabase.net/k970505/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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