

K003534 PENTRA 5DDec 1, 2000
15 days to decisionK003534 · Product code: **JPK** · Hematology
Source: <https://www.510kdatabase.net/k003534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Nov 16, 2000
Decision date	Dec 1, 2000
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	R&D Systems, Inc.
Location	Mchenry, IL, US
Contact	KENNETH T EDDES
510(k) history	79 submissions · 79 cleared · 1978-2016

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