

K984216 IMMUNO-TROL CONTROL CELLSMar 16, 1999
112 days to decisionK984216 · Product code: **JPK** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Nov 24, 1998
Decision date	Mar 16, 1999
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coulter Corp.
Location	Hialeah, FL, US
Contact	MARION S GAIDE
510(k) history	51 submissions · 51 cleared · 1989-2000

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