

K050709 RESOLVE HEMOGLOBIN KIT, JB-2 STAINING SYSTEM, MODELS FR-9120, FR-9400, FR-9360, FR-9367Mar 8, 2006
355 days to decisionK050709 · Product code: **GKA** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Mar 18, 2005
Decision date	Mar 8, 2006
Days to decision	355 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wallac OY
Location	Finland, FI
Contact	RAIJA KOSKIVAARA
510(k) history	22 submissions · 21 cleared · 1992-2014

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