

K973274 ACCUCOLOR HIGH CALIBRATOR (A3089)Oct 31, 1997
59 days to decisionK973274 · Product code: **GIZ** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Control, Normal (GIZ)
Date received	Sep 2, 1997
Decision date	Oct 31, 1997
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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