

K973649 HEMOSITE TEST SYSTEMAug 31, 1998
340 days to decisionK973649 · Product code: **KHG** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Whole Blood Hemoglobin Determination (KHG)
Date received	Sep 25, 1997
Decision date	Aug 31, 1998
Days to decision	340 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gds Technology, LLC
Location	Elkhart, IN, US
Contact	JONATHAN A KOVACH
510(k) history	7 submissions · 7 cleared · 1988-2000

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