

K973869 TRACE REAGENT LINE FOR THE COBAS MIRAJan 7, 1998
105 days to decisionK973869 · Product code: **CKA** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Alt/sgpt (CKA)
Date received	Sep 24, 1997
Decision date	Jan 7, 1998
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trace America, Inc.
Location	Miami, FL, US
Contact	David Johnston
510(k) history	22 submissions · 22 cleared · 1988-2001

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