

K002930 INSTACULTJan 22, 2001
124 days to decisionK002930 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k002930/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Sep 20, 2000
Decision date	Jan 22, 2001
Days to decision	124 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medtek Diagnostics, LLC
Location	Research Triangle Park, NC, US
Contact	LIANE F GOSSET
510(k) history	1 submissions · 1 cleared · 2001-2001

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