

K102664 HEMA SCREEN ERJan 28, 2011
135 days to decisionK102664 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k102664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reagent, Occult Blood (KHE)
Date received	Sep 15, 2010
Decision date	Jan 28, 2011
Days to decision	135 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Immunostics Inc.,
Location	Ocean, NJ, US
Contact	RICHARD M PEOPLES
510(k) history	14 submissions · 14 cleared · 1997-2023

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