

K171484 hema-screen SPECIFIC GoldJun 14, 2017
23 days to decisionK171484 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k171484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reagent, Occult Blood (KHE)
Date received	May 22, 2017
Decision date	Jun 14, 2017
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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