

**K060463 HEMA SCREEN SPECIFIC IFOBT**Jun 6, 2006  
104 days to decisionK060463 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k060463/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Feb 22, 2006
Decision date	Jun 6, 2006
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Immunostics Inc.,</b>
Location	Ocean, NJ, US
Contact	JEFFREY FLEISHMAN
510(k) history	14 submissions · 14 cleared · 1997-2023

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