

**K163554 hema-screen ER XCEL Enhanced Readability Fecal Occult Blood Test**

Jan 17, 2017  
29 days to decision

K163554 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k163554/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reagent, Occult Blood (KHE)
Date received	Dec 19, 2016
Decision date	Jan 17, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k163554/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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