

K170548 InSure ONEOct 5, 2017
223 days to decisionK170548 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k170548/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Feb 24, 2017
Decision date	Oct 5, 2017
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Enterix, Inc.
Location	Falmouth,, ME, US
Contact	Michele Houldsworth
510(k) history	3 submissions · 3 cleared · 2001-2017

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