

**K100817 BIOSIGN IFOBTEST, BIOSIGN FECAL OCCULT BLOOD TEST**Jul 1, 2010  
104 days to decisionK100817 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k100817/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Mar 19, 2010
Decision date	Jul 1, 2010
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Princeton BioMeditech Corp.</b>
Location	Monmouth Junction, NJ, US
Contact	JEMO KANG, PH.D.
510(k) history	72 submissions · 72 cleared · 1994-2025

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