

K101831 ENTERIX INSUREFIT FOB CONTROLS, MODEL 16800Oct 1, 2010
92 days to decisionK101831 · Product code: **OSL** · Hematology
Source: <https://www.510kdatabase.net/k101831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Fecal Occult Blood (OSL)
Date received	Jul 1, 2010
Decision date	Oct 1, 2010
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionostics, Inc.
Location	Mchenry, IL, US
Contact	MINNA RANNIKKO
510(k) history	49 submissions · 49 cleared · 1983-2013

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