

K163225 AFIAS iFOB with AFIAS-50Aug 8, 2017
264 days to decisionK163225 · Product code: **OOX** · Hematology
Source: <https://www.510kdatabase.net/k163225/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Occult Blood Analyzer (OOX)
Date received	Nov 17, 2016
Decision date	Aug 8, 2017
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163225/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026