

**K083744 BINAXNOW MALARIA POSITIVE CONTROL KIT,
MODEL 665-010**Sep 1, 2009
259 days to decisionK083744 · Product code: **MJZ** · Microbiology
Source: <https://www.510kdatabase.net/k083744/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Direct Antigen, Positive Control (MJZ)
Date received	Dec 16, 2008
Decision date	Sep 1, 2009
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Binax, Inc.
Location	S. Portland, ME, US
Contact	Anne Jepson
510(k) history	30 submissions · 30 cleared · 1986-2010

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