

**K070522 MODIFICATION TO: BINAX NOW LEGIONELLA
URINARY ANTIGEN TEST, #852-000,852-012**Mar 15, 2007
20 days to decisionK070522 · Product code: **MJH** · Microbiology
Source: <https://www.510kdatabase.net/k070522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Legionella, Spp., Elisa (MJH)
Date received	Feb 23, 2007
Decision date	Mar 15, 2007
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inverness Medical Professional Diagnostics
Location	Scarborough, ME, US
Contact	KAREN MORTIMER
510(k) history	1 submissions · 1 cleared · 2007-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070522/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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