FDA 510(k) Premarket Notification

# K070522 MODIFICATION TO: BINAX NOW LEGIONELLA URINARY ANTIGEN TEST, #852-000,852-012

**CLEARED**

Mar 15, 2007
20 days to decision

K070522 · 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 |