

K050352 IN-VITRO DIAGNOSTIC VAGINITIS TEST KITSep 1, 2005
202 days to decisionK050352 · Product code: **JTO** · Chemistry
Source: <https://www.510kdatabase.net/k050352/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Discs, Strips And Reagents, Microorganism Differentiation (JTO) |
| Date received | Feb 11, 2005 |
| Decision date | Sep 1, 2005 |
| Days to decision | 202 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ameritek Research, LLC |
| Location | Mill Creek, WA, US |
| Contact | KUD CHAIANG YEE |
| 510(k) history | 1 submissions · 1 cleared · 2005-2005 |

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