

K113253 ACE AXCEL CLINICAL CHEMISTRY SYSTEM,ACE ALBUMIN REAGENT,ACE TOTAL PROTEIN REAGENT,ACE BUN/UREANITROGEN REAGENTMay 17, 2012
197 days to decisionK113253 · Product code: **JJE** · Chemistry
Source: <https://www.510kdatabase.net/k113253/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE) |
| Date received | Nov 2, 2011 |
| Decision date | May 17, 2012 |
| Days to decision | 197 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Alfa Wassermann Diagnostic Technologies, Inc. |
| Location | West Caldwell, NJ, US |
| Contact | HYMAN KATZ |
| 510(k) history | 21 submissions · 21 cleared · 2008-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113253/> 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 June 8, 2026