

**K033860 AUTOKIT TOTAL KETONE BODIES KIT (SERUM) AND
WAKO KETONE BODY CALIBRATOR**Apr 23, 2004
133 days to decisionK033860 · Product code: JIT · Chemistry
Source: <https://www.510kdatabase.net/k033860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Dec 12, 2003
Decision date	Apr 23, 2004
Days to decision	133 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Wako Chemicals USA, Inc.
Location	Mchenry, IL, US
Contact	TONYA MALLORY
510(k) history	124 submissions · 123 cleared · 1981-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033860/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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