

**K992397 ACCUNATE-ONE STEP, ACCUNATE-ONE STEP
CASSETTE**Aug 26, 1999
38 days to decisionK992397 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k992397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jul 19, 1999
Decision date	Aug 26, 1999
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cenogenics Corp.
Location	Morganville, NJ, US
Contact	NITZA KATZ
510(k) history	5 submissions · 5 cleared · 1985-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992397/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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