

K990578 OSOM CARD II HCG-URINE TEST, MODEL 102Mar 9, 1999
14 days to decisionK990578 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k990578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Feb 23, 1999
Decision date	Mar 9, 1999
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wyntek Diagnostics, Inc.
Location	San Diego, CA, US
Contact	SHU-CHING CHENG
510(k) history	12 submissions · 12 cleared · 1995-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990578/> 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 29, 2026