

**K953383 WYNTEK OSOM HCG-URINE TEST**Aug 29, 1995  
41 days to decisionK953383 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k953383/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jul 19, 1995
Decision date	Aug 29, 1995
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953383/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026