

K973879 OSOM CARD HCG-URINE TESTNov 4, 1997
55 days to decisionK973879 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k973879/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Sep 10, 1997
Decision date	Nov 4, 1997
Days to decision	55 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

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