

K965227 OSOM CLASSIC HCG-URINE TEST (115)Feb 4, 1997
36 days to decisionK965227 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k965227/>**SUBMISSION DETAILS**

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|-----------------------|-----------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Dec 30, 1996 |
| Decision date | Feb 4, 1997 |
| Days to decision | 36 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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