

**K970424 EXCEL ONE STEP URINE HCG PREGNANCY
DIPSTICK TEST**Mar 6, 1997
30 days to decisionK970424 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k970424/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Feb 4, 1997 |
| Decision date | Mar 6, 1997 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Excel Scientific, Inc. |
| Location | Yorba Linda, CA, US |
| Contact | MIN-LEE CHENG |
| 510(k) history | 8 submissions · 8 cleared · 1996-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970424/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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