

K963231 EXCEL ONESTEP URINE HCG MODULE PREGNANCY TEST

Dec 4, 1996
107 days to decision

K963231 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k963231/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 19, 1996
Decision date	Dec 4, 1996
Days to decision	107 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

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Device record: <https://www.510kdatabase.net/k963231/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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