

K981512 ICON FXHCG URINE/SERUM TEST, ICON FXHCG URINE TEST, MODELS 40025,40050, 40005 & 41025May 28, 1998
30 days to decisionK981512 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k981512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 28, 1998
Decision date	May 28, 1998
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Skd, Inc. A Beckman Coulter Co.
Location	Palo Alto, CA, US
Contact	KAREN RICHARDS
510(k) history	1 submissions · 1 cleared · 1998-1998

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