

K811398 EARLY PREGNANCY DETECTIONMay 29, 1981
11 days to decisionK811398 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k811398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	May 18, 1981
Decision date	May 29, 1981
Days to decision	11 days
Third-party review	No

APPLICANT

Company	Immucem Corp.
Location	Mchenry, IL, US
510(k) history	18 submissions · 18 cleared · 1979-1988

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Device record: <https://www.510kdatabase.net/k811398/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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