

K862262 HCG MAIACLONE IMMUNORADIOMETRIC KIT/KIT COMPONENTSJul 29, 1986
46 days to decisionK862262 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k862262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jun 13, 1986
Decision date	Jul 29, 1986
Days to decision	46 days
Third-party review	No

APPLICANT

Company	Serono Diagnostics, Inc.
Location	Walker, MI, US
Contact	PHILIP M FANTASIA
510(k) history	25 submissions · 25 cleared · 1984-1996

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