

K862813 FSH MAIACLONE IMMUNORADIOMETRIC ASSAY KITSep 16, 1986
54 days to decisionK862813 · Product code: **CGJ** · Chemistry
Source: <https://www.510kdatabase.net/k862813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Jul 24, 1986
Decision date	Sep 16, 1986
Days to decision	54 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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