

**K864677 TSH MAIACLONE IMMUNORADIOMETRIC ASSAY
KIT/MAG SEP**Jan 7, 1987
36 days to decisionK864677 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k864677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Dec 2, 1986
Decision date	Jan 7, 1987
Days to decision	36 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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