

**K872627 FSH SEROZYME IMMUNOENZYMETRIC ASSAY  
KIT/MAG SEP PH**Jul 21, 1987  
15 days to decisionK872627 · Product code: **CGJ** · Chemistry  
Source: <https://www.510kdatabase.net/k872627/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Jul 6, 1987
Decision date	Jul 21, 1987
Days to decision	15 days
Third-party review	No

**APPLICANT**

---

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k872627/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026