

**K843930 IRMA IMMUNORADIOMETRIC ASSAY-FSH 125I**Oct 30, 1984  
25 days to decisionK843930 · Product code: **CGJ** · Immunology  
Source: <https://www.510kdatabase.net/k843930/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Oct 5, 1984
Decision date	Oct 30, 1984
Days to decision	25 days
Third-party review	No

**APPLICANT**

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Company	<b>Euro-Diagnostics BV</b>
Location	Mchenry, IL, US
Contact	PAUL M SZUTOWICZ
510(k) history	5 submissions · 5 cleared · 1984-1985

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k843930/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 1, 2026