

K841947 ESTRADIOL DIRECT RADIOIMMUNOASSAY KITJun 25, 1984
42 days to decisionK841947 · Product code: **CHP** · Chemistry
Source: <https://www.510kdatabase.net/k841947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	May 14, 1984
Decision date	Jun 25, 1984
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Sorin Biomedica, Fiat, USA, Inc.
Location	Mchenry, IL, US
510(k) history	20 submissions · 20 cleared · 1980-1994

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Device record: <https://www.510kdatabase.net/k841947/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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