

**K830563 CORTISOL RADIOIMMUNOASSAY KIT-CORTCTK**May 13, 1983  
79 days to decisionK830563 · Product code: **CGR** · Chemistry  
Source: <https://www.510kdatabase.net/k830563/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Radioimmunoassay, Cortisol (CGR)   |
| Date received         | Feb 23, 1983                       |
| Decision date         | May 13, 1983                       |
| Days to decision      | 79 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k830563/> 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 May 26, 2026