

**K884498 COTUBE LH IRMA ASSAY**Dec 22, 1988  
57 days to decisionK884498 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k884498/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Radioimmunoassay, Luteinizing Hormone (CEP) |
| Date received         | Oct 26, 1988                                |
| Decision date         | Dec 22, 1988                                |
| Days to decision      | 57 days                                     |
| Third-party review    | No  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Bio-Rad</b>  |
| Location       | Mchenry, IL, US   |
| Contact        | FRANK MATARRESE   |
| Website        | <a href="http://www.bio-rad.com">http://www.bio-rad.com</a> |
| 510(k) history | 319 submissions · 319 cleared · 1976-2017                   |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k884498/> 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 14, 2026