

**K885198 17-ALPHA-HYDROXYPROGESTERONE (17-OH-P)  
NEO. RIA**Feb 23, 1989  
69 days to decisionK885198 · Product code: **JLX** · Chemistry  
Source: <https://www.510kdatabase.net/k885198/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, 17-hydroxyprogesterone (JLX)
Date received	Dec 16, 1988
Decision date	Feb 23, 1989
Days to decision	69 days
Third-party review	No

**APPLICANT**

---

Company	<b>Icn Biomedicals, Inc.</b>
Location	Carson, CA, US
Contact	ROBERT HUDAK
510(k) history	11 submissions · 11 cleared · 1988-2003

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k885198/>; 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 June 28, 2026