

**K943188 SEALITE SCIENCE, INC. AQUALITE(R) LH**Oct 20, 1994  
107 days to decisionK943188 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k943188/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Jul 5, 1994
Decision date	Oct 20, 1994
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sealite Sciences, Inc.</b>
Location	Bogart, GA, US
Contact	DAVID F SMITH
510(k) history	11 submissions · 11 cleared · 1994-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943188/> 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 30, 2026