

**K905769 IMMULITE HS-TSH**Jan 31, 1991  
35 days to decisionK905769 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k905769/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Dec 27, 1990
Decision date	Jan 31, 1991
Days to decision	35 days
Third-party review	No

**APPLICANT**

---

Company	<b>Cirrus Diagnostics, Inc.</b>
Location	Chester, NJ, US
Contact	ROBERT FENNELL
510(k) history	10 submissions · 10 cleared · 1991-1992

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905769/>; 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 29, 2026