

**K897138 AFFINITY(TM) HTSH(TM)**Mar 9, 1990  
72 days to decisionK897138 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k897138/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Dec 27, 1989
Decision date	Mar 9, 1990
Days to decision	72 days
Third-party review	No

**APPLICANT**

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Company	<b>Bd Becton Dickinson Vacutainer Systems Preanalytic</b>
Location	Washington, DC, US
Contact	J ARNSBERGER
510(k) history	632 submissions · 625 cleared · 1976-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k897138/>; 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 21, 2026