

**K943195 COAT-A-COUNT NEONATAL TSH IRMA**Mar 13, 1995  
251 days to decisionK943195 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k943195/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jul 5, 1994
Decision date	Mar 13, 1995
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Diagnostic Products Corp.</b>
Location	Mchenry, IL, US
Contact	KENNETH B ASARCH
510(k) history	321 submissions · 321 cleared · 1976-2006

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