

**K012559 POLY STAT HCG TEST**Oct 16, 2001  
69 days to decisionK012559 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k012559/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 8, 2001
Decision date	Oct 16, 2001
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Bion Diagnostic Sciences</b>
Location	Redmond, WA, US
Contact	HELEN LANDICHO
510(k) history	1 submissions · 1 cleared · 2001-2001

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