

**K052000 ARCHITECT CA 19-9XR ASSAY**Oct 25, 2005  
92 days to decisionK052000 · Product code: **NIG** · Immunology  
Source: <https://www.510kdatabase.net/k052000/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carbohydrate Antigen (ca19-9), For Monitoring And Management Of Pancreatic Cancer (NIG)
Date received	Jul 25, 2005
Decision date	Oct 25, 2005
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujirebio Diagnostics,Inc.</b>
Location	North Caldwell, NJ, US
Contact	DIANA L WOLANIUK
510(k) history	45 submissions · 43 cleared · 1989-2025

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