

**K020566 FUJIREBIO DIAGNOSTICS CA 19-9 RIA**May 9, 2002  
78 days to decisionK020566 · Product code: **NIG** · Immunology  
Source: <https://www.510kdatabase.net/k020566/>**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	Feb 20, 2002
Decision date	May 9, 2002
Days to decision	78 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	DANIEL J O'CONNOR;SHANNESSY
510(k) history	45 submissions · 43 cleared · 1989-2025

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