

K052889 VITROS CA 19-9Dec 20, 2005
68 days to decisionK052889 · Product code: **NIG** · Immunology
Source: <https://www.510kdatabase.net/k052889/>**SUBMISSION DETAILS**

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	Oct 13, 2005
Decision date	Dec 20, 2005
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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