

**K191973 Lumpipulse G CA19-9-N**Oct 22, 2019  
90 days to decisionK191973 · Product code: **NIG** · Immunology  
Source: <https://www.510kdatabase.net/k191973/>**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 24, 2019
Decision date	Oct 22, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujirebio Dianostics, Inc.</b>
Location	Malvern, PA, US
Contact	Kristin Maddaloni
510(k) history	1 submissions · 1 cleared · 2019-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191973/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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