

K031393 BAYER ADVIA CENTAUR CA 19-9 ASSAYJun 24, 2003
53 days to decisionK031393 · Product code: **NIG** · Immunology
Source: <https://www.510kdatabase.net/k031393/>**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	May 2, 2003
Decision date	Jun 24, 2003
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Healthcare, LLC
Location	New York, NY, US
Contact	KENNETH T EDDES
510(k) history	46 submissions · 46 cleared · 2003-2018

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