

K023239 AIA-PACK CA 19-9Dec 23, 2002
87 days to decisionK023239 · Product code: **NIG** · Immunology
Source: <https://www.510kdatabase.net/k023239/>**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	Sep 27, 2002
Decision date	Dec 23, 2002
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tosoh Corp.
Location	Washington, DC, US
Contact	JUDITH E LOEBEL
Website	http://www.tosoh.com/
510(k) history	11 submissions · 11 cleared · 1990-2002

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