

**K023240 ST AIA-PACK CA 19-9**Dec 23, 2002  
87 days to decisionK023240 · Product code: **NIG** · Immunology  
Source: <https://www.510kdatabase.net/k023240/>**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	Sep 27, 2002
Decision date	Dec 23, 2002
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k023240/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026