

**K984359 AIA-PACK TROPONIN I ASSAY**Dec 23, 1998  
16 days to decisionK984359 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k984359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Dec 7, 1998
Decision date	Dec 23, 1998
Days to decision	16 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Tosoh Medics, Inc.</b>
Location	Washington, DC, US
Contact	LORI ROBINSON
510(k) history	41 submissions · 41 cleared · 1990-2002

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