

**K974075 ACCESS TROPONIN I REAGENTS ON THE ACCESS  
IMMUNOASSAY ANALYZER**Nov 10, 1997  
12 days to decisionK974075 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k974075/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Oct 29, 1997
Decision date	Nov 10, 1997
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Beckman Instruments, Inc.</b>
Location	Mchenry, IL, US
Contact	JAN OLSEN
Website	<a href="https://www.beckman.com">https://www.beckman.com</a>
510(k) history	281 submissions · 281 cleared · 1976-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974075/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 22, 2026