

**K993034 MEDICA INDIRECT IMMUNOFLUORESCENCE (IIF)  
ANTI- ENDOMYSIAL ANTIBODY (AEMA) TEST KIT, MODEL  
6001-ESD**Nov 1, 1999  
53 days to decisionK993034 · Product code: **MVM** · Immunology  
Source: <https://www.510kdatabase.net/k993034/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Sep 9, 1999
Decision date	Nov 1, 1999
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medica, Inc.</b>
Location	Encinitas, CA, US
Contact	RHODORA CHAPOCO
510(k) history	1 submissions · 1 cleared · 1999-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k993034/>; 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