

**K945607 VARELISA M2 ANTIBODIES**Jan 24, 1995  
70 days to decisionK945607 · Product code: **DBM** · Immunology  
Source: <https://www.510kdatabase.net/k945607/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Nov 15, 1994
Decision date	Jan 24, 1995
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Elias U.S.A., Inc.</b>
Location	Osceola, WI, US
Contact	CLAUS MUELLER
510(k) history	54 submissions · 54 cleared · 1992-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945607/> 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