

**K951206 VARELISA PARIETAL CELL ANTIBODIES**Apr 17, 1995  
31 days to decisionK951206 · Product code: **MLE** · Immunology  
Source: <https://www.510kdatabase.net/k951206/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Antiparietal Cell Antibody, Antigen, Control (MLE)
Date received	Mar 17, 1995
Decision date	Apr 17, 1995
Days to decision	31 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951206/> 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