

**K831292 ANTI-ENA TEST**Jul 18, 1983  
89 days to decisionK831292 · Product code: **LKO** · Immunology  
Source: <https://www.510kdatabase.net/k831292/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-rnp Antibody, Antigen And Control (LKO)
Date received	Apr 20, 1983
Decision date	Jul 18, 1983
Days to decision	89 days
Third-party review	No

**APPLICANT**

---

Company	<b>Meloy Laboratories, Inc.</b>
Location	Mchenry, IL, US
510(k) history	15 submissions · 15 cleared · 1977-1985

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k831292/> 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