

**K932206 SYNELISA ANA PROFILE**Dec 3, 1993  
211 days to decisionK932206 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k932206/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                             |
| Submission type       | Traditional  |
| Device classification | Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM) |
| Date received         | May 6, 1993  |
| Decision date         | Dec 3, 1993  |
| Days to decision      | 211 days   |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k932206/> 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