

**K952253 ENZYME IMMUNOASSAY ENA PLUS SCREENING
TEST KIT**Aug 24, 1995
101 days to decisionK952253 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k952253/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Extractable Antinuclear Antibody, Antigen And Control (LLL) |
| Date received | May 15, 1995 |
| Decision date | Aug 24, 1995 |
| Days to decision | 101 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Helix Diagnostics, Inc. |
| Location | West Sacramento, CA, US |
| Contact | VIRGINIA L CAPPEL |
| 510(k) history | 15 submissions · 15 cleared · 1991-2000 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952253/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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