FDA 510(k) Premarket Notification

# K253367 EliA CTD 13 Screen

**CLEARED**

Jun 25, 2026
268 days to decision

K253367 · Product code: **LLL** · Immunology
Source: https://www.510kdatabase.net/k253367/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Extractable Antinuclear Antibody, Antigen And Control (LLL) |
| Date received | Sep 30, 2025 |
| Decision date | Jun 25, 2026 |
| Days to decision | 268 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Phadia AB** |
| Location | Uppsala, SE |
| Contact | Darleen Welford |
| Website | http://www.phadia.com |
| 510(k) history | 33 submissions · 33 cleared · 2007-2026 |

Phadia AB is a medical products company headquartered in Uppsala, Sweden. The company develops, manufactures, and markets blood test systems for clinical diagnosis and monitoring of allergy, asthma, and autoimmune diseases. Phadia AB received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus is entirely on Immunology devices. Clearances span from 2007 to 2022, establishing a consistent track record in immunoassay and allergen testing technologies. The company's cleared devices include immunoassay systems for...

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k253367/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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