

**K182353 EliA CENP Immunoassay, EliA U1RNP Immunoassay,  
EliA RNP70 Immunoassay**Nov 27, 2018  
90 days to decisionK182353 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k182353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Aug 29, 2018
Decision date	Nov 27, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Phadia AB</b>
Location	Uppsala, SE
Contact	Carina Magnusson
Website	<a href="http://www.phadia.com">http://www.phadia.com</a>
510(k) history	32 submissions · 32 cleared · 2007-2022

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...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Phadia US, Inc.</b>
Contact	Sheryl Skinner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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

Device record: <https://www.510kdatabase.net/k182353/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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