

K190710 EliA SymphonyS ImmunoassayNov 29, 2019
255 days to decisionK190710 · Product code: **LLL** · Immunology
Source: <https://www.510kdatabase.net/k190710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Mar 19, 2019
Decision date	Nov 29, 2019
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Phadia AB
Location	Uppsala, SE
Contact	Carina Magnusson
Website	http://www.phadia.com
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

Consulting firm	Phadia US, Inc.
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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Device record: <https://www.510kdatabase.net/k190710/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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