FDA 510(k) Premarket Notification

K210902 EliA Ro52, EliA Ro60

CLEARED

Jul 27, 2022
488 days to decision

K210902 · Product code: **LKJ** · Immunology
Source: https://www.510kdatabase.net/k210902/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Mar 26, 2021
Decision date	Jul 27, 2022
Days to decision	488 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Phadia AB**
Location	Uppsala, SE
Contact	Sheryl Skinner
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 Lnc.**
Contact	Jane R Anthony

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