FDA 510(k) Premarket Notification

K202541 EliA RNA Pol III

CLEARED

Sep 13, 2021
376 days to decision

K202541 · Product code: **NYO** · Immunology
Source: https://www.510kdatabase.net/k202541/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Anti-ribonucleic Acid Polymerase (rnap) Iii Antibody (NYO)
Date received	Sep 2, 2020
Decision date	Sep 13, 2021
Days to decision	376 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, Inc.**
Contact	Sheryl Skinner

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