FDA 510(k) Premarket Notification

K173792 EliA PR3s Immunoassay

CLEARED

Mar 13, 2018
89 days to decision

K173792 · Product code: **MOB** · Immunology
Source: https://www.510kdatabase.net/k173792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Dec 14, 2017
Decision date	Mar 13, 2018
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary
Other names	EliA MPOs Immunoassay; EliA GBM Immunoassay

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...