FDA 510(k) Premarket Notification

K071913 IMMUNOCAP ALLERGEN F338, SCALLOP WITH MODEL(S): 14-4895-01

CLEARED

Aug 24, 2007
44 days to decision

K071913 · Product code: **DHB** · Immunology
Source: https://www.510kdatabase.net/k071913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Jul 11, 2007
Decision date	Aug 24, 2007
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Phadia AB**
Location	Uppsala, SE
Contact	KARL-ERIK BACKLUND
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...