

K173704 ImmunoCAP Tryptase, ImmunoCAP Tryptase Calibrators, ImmunoCAP Tryptase Curve Control, ImmunoCAP Tryptase Conjugate 50, ImmunoCAP Tryptase Calibrator Strip, ImmunoCAP Tryptase Curve Control Strip

Mar 2, 2018
88 days to decision

K173704 · Product code: OYL · Immunology
Source: <https://www.510kdatabase.net/k173704/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tryptase Assay System (OYL)
Date received	Dec 4, 2017
Decision date	Mar 2, 2018
Days to decision	88 days
Third-party review	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...

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Device record: <https://www.510kdatabase.net/k173704/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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