

K161899 ImmunoCAP Total IgE Calibrator Strip/Total IgE Curve Control Strip, ImmunoCAP Total IgE Calibrators/Total IgE Curve Controls, ImmunoCAP Specific IgE Calibrator Strip/Specific IgE Curve Control Strip, ImmunoCAP Specific IgE Calibrators/Specific IgE Curve Controls

Jul 28, 2016
17 days to decision

K161899 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k161899/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Jul 11, 2016
Decision date	Jul 28, 2016
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Phadia AB
Location	Uppsala, SE
Contact	Ulf Karlberg
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/k161899/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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