

K151799 EliA anti-TG Immunoassay, EliA anti-TPO Immunoassay, EliA Thyroid Positive Control 250, EliA Thyroid Positive Control 2500/5000Mar 25, 2016
267 days to decisionK151799 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k151799/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Jul 2, 2015
Decision date	Mar 25, 2016
Days to decision	267 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...