

K241456 GlutenID Celiac Genetic Health Risk TestJan 7, 2025
230 days to decisionK241456 · Product code: **PTA** · Immunology
Source: <https://www.510kdatabase.net/k241456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Genetic Variant Detection And Health Risk Assessment System (PTA)
Date received	May 22, 2024
Decision date	Jan 7, 2025
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Targeted Genomics, LLC
Location	Irvine, CA, US
Contact	Shelly Gunn
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Bhoomika Joyappa

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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