

K062787 ELIA CELIKEY IGA WELL, MODEL 14-5517-01Dec 29, 2006
102 days to decisionK062787 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k062787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Sep 18, 2006
Decision date	Dec 29, 2006
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary
Other names	ELIA CELIAC CONTROL, MODEL 83-1011-01

APPLICANT

Company	Phadia US, Inc.
Location	Portae, MI, US
Contact	MARTIN R MANN
510(k) history	22 submissions · 21 cleared · 2006-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062787/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026