

K102490 IGX PLEX CELIAC QUALITATIVE ASSAYJun 2, 2011
275 days to decisionK102490 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k102490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Aug 31, 2010
Decision date	Jun 2, 2011
Days to decision	275 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sqi Diagnostics Systems
Location	Toronto, On, CA
Contact	Kate Smith
510(k) history	2 submissions · 2 cleared · 2009-2011

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