

K994379 EU-TTG IGA ELISAFeb 18, 2000
53 days to decisionK994379 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k994379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Dec 27, 1999
Decision date	Feb 18, 2000
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Scimedx Corp.
Location	Denvill, NJ, US
Contact	Gary Lehnus
510(k) history	14 submissions · 14 cleared · 1996-2001

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