

K011348 PHASE II GBM IGG ANTIBODY EIA TESTJun 25, 2001
54 days to decisionK011348 · Product code: **MVJ** · Immunology
Source: <https://www.510kdatabase.net/k011348/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices, Measure, Antibodies To Glomerular Basement Membrane (gbm) (MVJ)
Date received	May 2, 2001
Decision date	Jun 25, 2001
Days to decision	54 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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