FDA 510(k) Premarket Notification

K010625 EUROSPITAL EU-TTG IGA UMANA

CLEARED

Apr 24, 2001
53 days to decision

K010625 · Product code: **MVM** · Immunology
Source: https://www.510kdatabase.net/k010625/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Mar 2, 2001
Decision date	Apr 24, 2001
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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k010625/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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