

**K002107 IFA KIT FOR THE DETECTION OF ENDOMYSIAL IGA ANIBODIES USING PRIMATE UMBILICAL CORD (PUC)-EMA/PUC LGA.**Aug 4, 2000  
23 days to decisionK002107 · Product code: **MVM** · Immunology  
Source: <https://www.510kdatabase.net/k002107/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Jul 12, 2000
Decision date	Aug 4, 2000
Days to decision	23 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Scimedx Corp.</b>
Location	Denvill, NJ, US
Contact	GARY LEHNUS,PH.D
510(k) history	14 submissions · 14 cleared · 1996-2001

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