

**K040095 IMMULISA ANTI-HUMAN TISSUE
TRANSGLUTAMINASE (HU-TTG) ANTIBODY TOTAL IGA/IGG
ELISA**Mar 5, 2004
45 days to decisionK040095 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k040095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Jan 20, 2004
Decision date	Mar 5, 2004
Days to decision	45 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Immco Diagnostics, Inc.
Location	Buffalo, NY, US
Contact	KEVIN J LAWSON
510(k) history	55 submissions · 55 cleared · 1988-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040095/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 30, 2026