

**K043433 AUTOSTAT II ANTI-TISSUE TRANSGLUTAMINASE IGG
ELISA**Mar 7, 2005
84 days to decisionK043433 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k043433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Dec 13, 2004
Decision date	Mar 7, 2005
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hycor Biomedical , Ltd.
Location	Penicuik, Midlothian, GB
Contact	DANIELLE M KNIGHT
510(k) history	4 submissions · 4 cleared · 2003-2005

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