

**K040466 BINDAZYME HUMAN ANTI TISSUE
TRANSGLUTAMINASE IGA AND IGG EIA DIAGNOSTIC TEST
KITS**Jul 16, 2004
144 days to decisionK040466 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k040466/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Feb 23, 2004
Decision date	Jul 16, 2004
Days to decision	144 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	The Binding Site
Location	Santa Monica, CA, US
Contact	JAY H GELLER
510(k) history	10 submissions · 10 cleared · 2004-2014

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