

**K041174 CELIKEY TTG (HUMAN, RECOMBINANT) IGA
ANTIBODIES MODEL #18148/18196**Jul 19, 2004
75 days to decisionK041174 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k041174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	May 5, 2004
Decision date	Jul 19, 2004
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sweden Diagnostics (Germany) GmbH
Location	Freiburg, DE
Contact	MICHAEL LINSS
510(k) history	8 submissions · 8 cleared · 2004-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041174/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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