

K041173 CELIKEY IGG ITG IGG ANTIBODIES, MODEL 17996Aug 2, 2004
89 days to decisionK041173 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k041173/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	May 5, 2004
Decision date	Aug 2, 2004
Days to decision	89 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

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