

K971464 IMMUNOSCAN ANTI-GBM QUANTITATIVE KITOct 29, 1997
190 days to decisionK971464 · Product code: **DBL** · Immunology
Source: <https://www.510kdatabase.net/k971464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Autoantibodies, Indirect Immunofluorescent, Antigen, Control (DBL)
Date received	Apr 22, 1997
Decision date	Oct 29, 1997
Days to decision	190 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Euro-Diagnostica AB
Location	Malmö, SE
Contact	KARL A POSSELT
510(k) history	6 submissions · 6 cleared · 1997-2010

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