

**K971690 IMMUNOSCAN PR3-ANCA**Oct 29, 1997  
175 days to decisionK971690 · Product code: **MOB** · Immunology  
Source: <https://www.510kdatabase.net/k971690/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	May 7, 1997
Decision date	Oct 29, 1997
Days to decision	175 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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