

**K971689 IMMUNOSCAN ANTI-MYELOPEROXIDASE
ANTIBODIES (MPO-ANCA) QUANTITATIVE KIT**Oct 29, 1997
175 days to decisionK971689 · Product code: **MOB** · Immunology
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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

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

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