

**K013283 RELISA PR3-ANCA TEST SYSTEM FOR ANTIBODIES TO PROTEINASE 3, MODEL # 7096-16**

Nov 14, 2001  
43 days to decision

K013283 · Product code: **MOB** · Immunology  
Source: <https://www.510kdatabase.net/k013283/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Oct 2, 2001
Decision date	Nov 14, 2001
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immuno Concepts, Inc.</b>
Location	Mchenry, IL, US
Contact	ERIC S HOY
510(k) history	36 submissions · 36 cleared · 1981-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k013283/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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