

**K983924 HEP-2000 COLORZYME ANA-RO TEST SYSTEM,  
MODEL 4200-RO**Dec 18, 1998  
44 days to decisionK983924 · Product code: **DHN** · Immunology  
Source: <https://www.510kdatabase.net/k983924/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Nov 4, 1998
Decision date	Dec 18, 1998
Days to decision	44 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/k983924/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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