

K972145 HEP-2000 FLUORESCENT ANA-RO TEST SYSTEMFeb 24, 1998
263 days to decisionK972145 · Product code: **DHN** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Jun 6, 1997
Decision date	Feb 24, 1998
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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