

K013213 HYPERION VISIQUANT ANA TEST KITJun 4, 2002
251 days to decisionK013213 · 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	Sep 26, 2001
Decision date	Jun 4, 2002
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hyperion, Inc.
Location	Mchenry, IL, US
Contact	RADHA GOOLABSINGH
510(k) history	8 submissions · 8 cleared · 1984-2002

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