

K970198 IFA HEP2 KIT FOR THE DETECTION OF ANTINUCLEAR ANTIBODIESFeb 20, 1997
30 days to decisionK970198 · 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	Jan 21, 1997
Decision date	Feb 20, 1997
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Scimedx Corp.
Location	Denvill, NJ, US
Contact	GARY LEHNUS PHD
510(k) history	14 submissions · 14 cleared · 1996-2001

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