

K964165 MICRO21 WITH NDNAJan 3, 1997
78 days to decisionK964165 · 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	Oct 17, 1996
Decision date	Jan 3, 1997
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Triangle Biomedical Sciences, Inc.
Location	Palm Beach Gardens, FL, US
Contact	R. OTTO STELLNER
510(k) history	6 submissions · 6 cleared · 1996-1998

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