

K043067 ENA IGG BEADCHIP TEST SYSTEM, ARRAY IMAGING SYSTEM, MODELS 800-00025, AIS 400May 31, 2005
204 days to decisionK043067 · Product code: LLL · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Nov 8, 2004
Decision date	May 31, 2005
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioarray Solutions, Ltd.
Location	Warren, NJ, US
Contact	KEVIN WYCKOFF
510(k) history	1 submissions · 1 cleared · 2005-2005

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