

K921746 VITEK IMMUNODIAGNOSTIC ASSAY SYSTEMJun 16, 1992
64 days to decisionK921746 · Product code: **CGJ** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Apr 13, 1992
Decision date	Jun 16, 1992
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Vitek, Inc.
Location	Hazelwood, MO, US
Contact	VICKI ANASTASI
510(k) history	49 submissions · 49 cleared · 1992-1998

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