

**K965213 STRATUS MYOGLOBIN GLUOROMETRIC ENZYME
IMMUNOASSAY**Feb 10, 1997
42 days to decisionK965213 · Product code: **DDR** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Dec 30, 1996
Decision date	Feb 10, 1997
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Intl., Inc.
Location	Deerfield, IL, US
Contact	RADHA GOOLABSINGH
510(k) history	30 submissions · 30 cleared · 1995-1998

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