

K923105 MILES URINE AMYLASE METHODSep 28, 1992
101 days to decisionK923105 · Product code: **JFJ** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jun 19, 1992
Decision date	Sep 28, 1992
Days to decision	101 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Heraeus Kulzer, Inc.
Location	Elkhart, IN, US
Contact	ROBERT L.HABIG
510(k) history	145 submissions · 145 cleared · 1988-2009

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