

K955115 VENOM TIEM REAGENTApr 3, 1996
146 days to decisionK955115 · Product code: **JCO** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bothrops Atrax Reagent (JCO)
Date received	Nov 9, 1995
Decision date	Apr 3, 1996
Days to decision	146 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medical Diagnostic Technologies, Inc.
Location	Augusta, GA, US
Contact	MICHAEL D BICK
510(k) history	57 submissions · 57 cleared · 1985-2006

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