

K992665 MACRA LP(A) ENZYME IMMUNOASSAY KITNov 26, 1999
109 days to decisionK992665 · Product code: **DFC** · Chemistry
Source: <https://www.510kdatabase.net/k992665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Aug 9, 1999
Decision date	Nov 26, 1999
Days to decision	109 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trinity Biotech USA
Location	Jamestown, NY, US
Contact	WAYNE A KVETKOSKY
510(k) history	11 submissions · 11 cleared · 1999-2014

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