

**K981734 VTEC-RPLA SEIKEN**Sep 22, 1998  
127 days to decisionK981734 · Product code: **GNA** · Microbiology  
Source: <https://www.510kdatabase.net/k981734/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Types, Escherichia Coli (GNA)
Date received	May 18, 1998
Decision date	Sep 22, 1998
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Denka Seiken&amp;apos;S</b>
Location	Tokyo, JP
Contact	KEVIN MANGAN
510(k) history	4 submissions · 4 cleared · 1998-2002

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