

K981829 IS EBV-EBNA-1 IGG ELISA TEST SYSTEMFeb 16, 1999
270 days to decisionK981829 · Product code: **GNP** · Microbiology
Source: <https://www.510kdatabase.net/k981829/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Cf, Epstein-barr Virus (GNP)
Date received	May 22, 1998
Decision date	Feb 16, 1999
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diamedix Corp.
Location	Miami, FL, US
Contact	NORMAN JENKINS
510(k) history	68 submissions · 68 cleared · 1986-2011

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