

K914801 IMMUNOWELL DSDNA ANTIBODY TESTDec 9, 1991
46 days to decisionK914801 · Product code: **DHC** · Immunology
Source: <https://www.510kdatabase.net/k914801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Systemic Lupus Erythematosus (DHC)
Date received	Oct 24, 1991
Decision date	Dec 9, 1991
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	General Biometrics, Inc.
Location	San Diego, CA, US
Contact	BRYAN L KIEHL
510(k) history	23 submissions · 23 cleared · 1989-1992

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