

K821385 SERO/TEX LE TESTMay 28, 1982
18 days to decisionK821385 · Product code: **DHC** · Immunology
Source: <https://www.510kdatabase.net/k821385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Systemic Lupus Erythematosus (DHC)
Date received	May 10, 1982
Decision date	May 28, 1982
Days to decision	18 days
Third-party review	No

APPLICANT

Company	Texas Immunology, Inc.
Location	Mchenry, IL, US
510(k) history	27 submissions · 27 cleared · 1982-1999

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Device record: <https://www.510kdatabase.net/k821385/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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