FDA 510(k) Premarket Notification

K821386 SERO/TEX MONO TEST

CLEARED

Jul 2, 1982
53 days to decision

K821386 · Product code: **KTN** · Immunology
Source: https://www.510kdatabase.net/k821386/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	May 10, 1982
Decision date	Jul 2, 1982
Days to decision	53 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k821386/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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