

K821000 ENZYMUNE-TEST DIGOXINApr 26, 1982
18 days to decisionK821000 · Product code: **DON** · Chemistry
Source: <https://www.510kdatabase.net/k821000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Digoxin (125-i), Rabbit Antibody, Solid Phase Sep. (DON)
Date received	Apr 8, 1982
Decision date	Apr 26, 1982
Days to decision	18 days
Third-party review	No

APPLICANT

Company	Icl Scientific
Location	Mchenry, IL, US
510(k) history	48 submissions · 48 cleared · 1976-1988

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Device record: <https://www.510kdatabase.net/k821000/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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