

K802358 OREIA-Q-DIGOct 10, 1980
14 days to decisionK802358 · Product code: **KXT** · Toxicology
Source: <https://www.510kdatabase.net/k802358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Sep 26, 1980
Decision date	Oct 10, 1980
Days to decision	14 days
Third-party review	No

APPLICANT

Company	Organon, Inc.
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1977-1995

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Device record: <https://www.510kdatabase.net/k802358/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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