

K894521 FPR DIGOXIN KITSep 25, 1989
67 days to decisionK894521 · Product code: **KXT** · Toxicology
Source: <https://www.510kdatabase.net/k894521/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Digoxin (KXT) |
| Date received | Jul 20, 1989 |
| Decision date | Sep 25, 1989 |
| Days to decision | 67 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Colony Laboratories, Inc. |
| Location | Washington, DC, US |
| Contact | DALE B HINSON |
| 510(k) history | 16 submissions · 16 cleared · 1989-1989 |

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