

K853021 OPTIMATE DIGOXIN TESTAug 7, 1985
20 days to decisionK853021 · Product code: **DPB** · Toxicology
Source: <https://www.510kdatabase.net/k853021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Digoxin (125-i), Rabbit Antibody, Charcoal Sep. (DPB)
Date received	Jul 18, 1985
Decision date	Aug 7, 1985
Days to decision	20 days
Third-party review	No

APPLICANT

Company	Miles Laboratories, Inc.
Location	Mchenry, IL, US
Contact	JOHN H ENGELMANN
510(k) history	158 submissions · 158 cleared · 1976-1988

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853021/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026