

K830035 SOPHEIA DIGITOXIN EIA KIT & COMPONENTSJan 28, 1983
21 days to decisionK830035 · Product code: **LFM** · Chemistry
Source: <https://www.510kdatabase.net/k830035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digitoxin (LFM)
Date received	Jan 7, 1983
Decision date	Jan 28, 1983
Days to decision	21 days
Third-party review	No

APPLICANT

Company	Diagnostic Products Corp.
Location	Mchenry, IL, US
510(k) history	321 submissions · 321 cleared · 1976-2006

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k830035/> 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 June 21, 2026