FDA 510(k) Premarket Notification

K830035 SOPHEIA DIGITOXIN EIA KIT & COMPONENTS

CLEARED

Jan 28, 1983
21 days to decision

K830035 · 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