FDA 510(k) Premarket Notification

K800035 PENTEX LIPOPROTEIN CHOLESTEROL SOLU.

CLEARED

Jan 21, 1980
14 days to decision

K800035 · Product code: **JJX** · Chemistry
Source: https://www.510kdatabase.net/k800035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jan 7, 1980
Decision date	Jan 21, 1980
Days to decision	14 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k800035/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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