FDA 510(k) Premarket Notification

K802432 GLYCO-TROL HUMAN GLYCOSYLATED HOM. CONT.

CLEARED

Dec 1, 1980
56 days to decision

K802432 · Product code: **LCP** · Hematology
Source: https://www.510kdatabase.net/k802432/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Oct 6, 1980
Decision date	Dec 1, 1980
Days to decision	56 days
Third-party review	No

APPLICANT

Company	**Clin Tech Diagnostics Corp.**
Location	Mchenry, IL, US
510(k) history	5 submissions · 5 cleared · 1980-1982