FDA 510(k) Premarket Notification

K832020 HEMOCUE PHOTOMETER TECHNICAL MANUAL

CLEARED

Oct 28, 1983
135 days to decision

K832020 · Product code: **GKR** · Hematology
Source: https://www.510kdatabase.net/k832020/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Jun 15, 1983
Decision date	Oct 28, 1983
Days to decision	135 days
Third-party review	No

APPLICANT

Company	**Aktiebolaget Leo Diagnostics**
Location	Walker, MI, US
510(k) history	1 submissions · 1 cleared · 1983-1983