FDA 510(k) Premarket Notification

K811567 ORTHO* BI-LEVEL ASSAYED GLYCOH. CONTR. S

CLEARED

Sep 16, 1981
104 days to decision

K811567 · Product code: **LCP** · Hematology
Source: https://www.510kdatabase.net/k811567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 4, 1981
Decision date	Sep 16, 1981
Days to decision	104 days
Third-party review	No

APPLICANT

Company	**Ortho Diagnostic Systems, Inc.**
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997