FDA 510(k) Premarket Notification

CLEARED

K090209 HEMOSIL LIQUID HEPARIN, HEPARIN CALIBRATORS AND LMW AND UF HEPARIN CONTROLS

Jun 2, 2009
125 days to decision

K090209 · Product code: **KFF** · Hematology
Source: https://www.510kdatabase.net/k090209/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Jan 28, 2009
Decision date	Jun 2, 2009
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Instrumentation Laboratory CO**
Location	Mchenry, IL, US
Contact	CAROL MARBLE
510(k) history	321 submissions · 320 cleared · 1976-2023