

**K083175 BERICHROM HEPARIN UF CALIBRATOR,
BERICHROM HEPARIN UF CONTROL 1, AND BERICHROM
HEPARIN UF CONTROL 2**

Jan 26, 2009
90 days to decision

K083175 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k083175/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Oct 28, 2008
Decision date	Jan 26, 2009
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	JANET M FOSE
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k083175/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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