

K223635 Sonoclot Coagulation & Platelet Function Analyzer System with Sonoclot ViewerJan 4, 2023
30 days to decisionK223635 · Product code: **JBP** · Hematology
Source: <https://www.510kdatabase.net/k223635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Activated Whole Blood Clotting Time (JBP)
Date received	Dec 5, 2022
Decision date	Jan 4, 2023
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sienco, Inc.
Location	Broomfield, CO, US
Contact	Jennifer Aiken
510(k) history	5 submissions · 5 cleared · 1995-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026