

K883689 ORTHO OWREN'S BUFFERNov 1, 1988
64 days to decisionK883689 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k883689/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Aug 29, 1988
Decision date	Nov 1, 1988
Days to decision	64 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883689/>; 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 14, 2026