FDA 510(k) Premarket Notification

K883689 ORTHO OWREN'S BUFFER

CLEARED

Nov 1, 1988
64 days to decision

K883689 · 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