FDA 510(k) Premarket Notification

K810058 ORTHO QUANTITATIVE FIBRINOGEN ASSAY

CLEARED

Feb 26, 1981
44 days to decision

K810058 · Product code: **KQJ** · Hematology
Source: https://www.510kdatabase.net/k810058/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Fibrinogen Determination (KQJ)
Date received	Jan 13, 1981
Decision date	Feb 26, 1981
Days to decision	44 days
Third-party review	No

APPLICANT

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