FDA 510(k) Premarket Notification

K811713 AVI-D CONTROL

CLEARED

Oct 23, 1981
128 days to decision

K811713 · Product code: **KSF** · Hematology
Source: https://www.510kdatabase.net/k811713/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Quality Control For Blood Banking Reagents (KSF)
Date received	Jun 17, 1981
Decision date	Oct 23, 1981
Days to decision	128 days
Third-party review	No

APPLICANT

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