FDA 510(k) Premarket Notification

K812002 ELUAID

CLEARED

Oct 28, 1981
106 days to decision

K812002 · Product code: **GGK** · Hematology
Source: https://www.510kdatabase.net/k812002/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Products, Red-cell Lysing Products (GGK)
Date received	Jul 14, 1981
Decision date	Oct 28, 1981
Days to decision	106 days
Third-party review	No

APPLICANT

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