FDA 510(k) Premarket Notification

K021923 INRATIO SELF-TEST

CLEARED

Oct 24, 2002
135 days to decision

K021923 · Product code: **GJS** · Hematology
Source: https://www.510kdatabase.net/k021923/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Jun 11, 2002
Decision date	Oct 24, 2002
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hemosense, Inc.**
Location	Milpitas, CA, US
Contact	Judith Blunt
510(k) history	3 submissions · 3 cleared · 2002-2007