FDA 510(k) Premarket Notification

K892209 APTT BY HEMOCHRON(R)

CLEARED

Jun 22, 1989
80 days to decision

K892209 · Product code: **GFO** · Hematology
Source: https://www.510kdatabase.net/k892209/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Apr 3, 1989
Decision date	Jun 22, 1989
Days to decision	80 days
Third-party review	No

APPLICANT

Company	**Intensive Technology, Inc.**
Location	Mchenry, IL, US
Contact	LES HEIMANN
510(k) history	12 submissions · 12 cleared · 1981-1993