FDA 510(k) Premarket Notification

K841523 OWREN'S VERONAL BUFFERR

CLEARED

Jun 1, 1984
50 days to decision

K841523 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k841523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Apr 12, 1984
Decision date	Jun 1, 1984
Days to decision	50 days
Third-party review	No

APPLICANT

Company	**Diatech, Inc.**
Location	Mchenry, IL, US
510(k) history	17 submissions · 17 cleared · 1984-1988