FDA 510(k) Premarket Notification

K890399 MODIFIED D-DI-TEST KIT

CLEARED

Feb 7, 1989
14 days to decision

K890399 · Product code: **GHH** · Hematology
Source: https://www.510kdatabase.net/k890399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Jan 24, 1989
Decision date	Feb 7, 1989
Days to decision	14 days
Third-party review	No

APPLICANT

Company	**American Bioproducts Co.**
Location	Parsippany, NJ, US
Contact	LOC B LE,PHD
510(k) history	79 submissions · 75 cleared · 1985-1998