FDA 510(k) Premarket Notification

K801268 HEMOGLOBIN CONTROL LEVELS

CLEARED

Jul 14, 1980
47 days to decision

K801268 · Product code: **KHG** · Hematology
Source: https://www.510kdatabase.net/k801268/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Whole Blood Hemoglobin Determination (KHG)
Date received	May 28, 1980
Decision date	Jul 14, 1980
Days to decision	47 days
Third-party review	No

APPLICANT

Company	**Bioscientific**
Location	Mchenry, IL, US
510(k) history	16 submissions · 16 cleared · 1978-1981