FDA 510(k) Premarket Notification

K884881 DADE PROTEIN C CHROMOGENIC ASSAY

CLEARED

Feb 2, 1989
72 days to decision

K884881 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k884881/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 22, 1988
Decision date	Feb 2, 1989
Days to decision	72 days
Third-party review	No

APPLICANT

Company	**Baxter Healthcare Corp**
Location	Mchenry, IL, US
Contact	JEANNE-MARIE VARGA
510(k) history	505 submissions · 496 cleared · 1977-2019